PAT T COOPERATION TREATY

From the INTERNATIONAL BUREAU

PCT

NOTIFICATION OF ELECTION

(PCT Rule 61.2)

To:

Commissioner
US Department of Commerce
United States Patent and Trademark Office, PCT
2011 South Clark Place Room
CP2/5C24
Arlington, VA 22202
ETATS-UNIS D'AMERIQUE

in its capacity as elected Office

Date of mailing (day/month/year) 15 June 2001 (15.06.01)	
International application No. PCT/US00/04374	**Applicant's or agent's file reference** ESTC004/01WO
International filing date (day/month/year) 18 February 2000 (18.02.00)	**Priority date** (day/month/year) 19 February 1999 (19.02.99)
Applicant BERTOLERO, Arthur, A. et al	

1. The designated Office is hereby notified of its election made:

[X] in the demand filed with the International Preliminary Examining Authority on:

15 September 2000 (15.09.00)

[ ] in a notice effecting later election filed with the International Bureau on:

2. The election [X] was

[ ] was not

made before the expiration of 19 months from the priority date or, where Rule 32 applies, within the time limit under Rule 32.2(b).

The International Bureau of WIPO **34, chemin des Colombettes** **1211 Geneva 20, Switzerland**	Authorized officer Antonia Muller
Facsimile No.: (41-22) 740.14.35	Telephone No.: (41-22) 338.83.38

09/913881

14

PATENT COOPERATION TREATY

PCT

INTERNATIONAL PRELIMINARY EXAMINATION REPORT

(PCT Article 36 and Rule 70)

Applicant's or agent's file reference ESTC004/01WO	**FOR FURTHER ACTION**	See Notification of Transmittal of International Preliminary Examination Report (Form PCT/IPEA/416)
International application No. PCT/US00/04374	International filing date *(day/month/year)* 18 February 2000 (18.02.2000)	Priority date *(day/month/year)* 19 February 1999 (19.02.1999)
International Patent Classification (IPC) or national classification and IPC IPC(7): A61M 29/00 and US Cl.: 604/102.01		
Applicant ENDOSCOPIC TECHNOLOGIES, INC. ET AL.		

1. This international preliminary examination report has been prepared by this International Preliminary Examining Authority and is transmitted to the applicant according to Article 36.

2. This REPORT consists of a total of 3 sheets, including this cover sheet.

   ☐ This report is also accompanied by ANNEXES, i.e., sheets of the description, claims and/or drawings which have been amended and are the basis for this report and/or sheets containing rectifications made before this Authority (see Rule 70.16 and Section 607 of the Administrative Instructions under the PCT).

   These annexes consist of a total of ___ sheets.

3. This report contains indications relating to the following items:

   - I ☒ Basis of the report
   - II ☐ Priority
   - III ☐ Non-establishment of report with regard to novelty, inventive step and industrial applicability
   - IV ☐ Lack of unity of invention
   - V ☒ Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
   - VI ☐ Certain documents cited
   - VII ☐ Certain defects in the international application
   - VIII ☐ Certain observations on the international application

Date of submission of the demand	Date of completion of this report
15 September 2000 (15.09.2000)	09 October 2001 (09.10.2001)
Name and mailing address of the IPEA/US Commissioner of Patents and Trademarks Box PCT Washington, D.C. 20231 Facsimile No. (703)305-3230	Authorized officer Richard Seidel Telephone No. 703.308.0858

Form PCT/IPEA/409 (cover sheet)(July 1998)

INTERNATIONAL PRELIMINARY EXAMINATION REPORT

International applicati[redacted]

PCT/US00/04374

I. Basis of the report

1. With regard to the elements of the international application:*

☒ the international application as originally filed.

☒ the description:
pages 1-40 as originally filed
pages NONE, filed with the demand
pages NONE, filed with the letter of _____.

☒ the claims:
pages 41-46, as originally filed
pages NONE, as amended (together with any statement) under Article 19
pages NONE, filed with the demand
pages NONE, filed with the letter of _____.

☒ the drawings:
pages 1-12, as originally filed
pages NONE, filed with the demand
pages NONE, filed with the letter of _____.

☐ the sequence listing part of the description:
pages NONE, as originally filed
pages NONE, filed with the demand
pages NONE, filed with the letter of _____.

2. With regard to the **language**, all the elements marked above were available or furnished to this Authority in the language in which the international application was filed, unless otherwise indicated under this item.
These elements were available or furnished to this Authority in the following language _____ which is:

☐ the language of a translation furnished for the purposes of international search (under Rule23.1(b)).

☐ the language of publication of the international application (under Rule 48.3(b)).

☐ the language of the translation furnished for the purposes of international preliminary examination(under Rules 55.2 and/or 55.3).

3. With regard to any **nucleotide and/or amino acid sequence** disclosed in the international application, the international preliminary examination was carried out on the basis of the sequence listing:

☐ contained in the international application in printed form.

☐ filed together with the international application in computer readable form.

☐ furnished subsequently to this Authority in written form.

☐ furnished subsequently to this Authority in computer readable form.

☐ The statement that the subsequently furnished written sequence listing does not go beyond the disclosure in the international application as filed has been furnished.

☐ The statement that the information recorded in computer readable form is identical to the written sequence listing has been furnished.

4. ☐ The amendments have resulted in the cancellation of:

☐ the description, pages NONE

☐ the claims, Nos. NONE

☐ the drawings, sheets/~~fig~~ NONE

5. ☐ This report has been established as if (some of) the amendments had not been made, since they have been considered to go beyond the disclosure as filed, as indicated in the Supplemental Box (Rule 70.2(c)).**

** Replacement sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this report as "originally filed" and are not annexed to this report since they do not contain amendments (Rules 70.16 and 70.17).*

*** Any replacement sheet containing such amendments must be referred to under item 1 and annexed to this report.*

V. Reasoned statement under Rule 66.2(a)(ii) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

1. STATEMENT

Novelty (N)	Claims 1-19	YES
	Claims 20	NO
Inventive Step (IS)	Claims NONE	YES
	Claims 1-20	NO
Industrial Applicability (IA)	Claims 1-20	YES
	Claims NONE	NO

2. CITATIONS AND EXPLANATIONS

Claims 1-19 lack an inventive step under PCT Article 33(3) as being obvious over Bertolero et al. (US 5,868,703) in view of Buckberg et al. (US 5,226,427).

Bertolero et al. disclose a multichannel catheter having a first channel (34), a second channel (36) and a third channel (38).

Bertolero et al. fails to disclose the obturator.

Buckberg et al. discloses a stylet (14) inserted into an empty lumen or passageway that extends along most of the length of the catheter.

It would have been obvious to have utilized the rigid stylet taught by Buckberg et al. with the multichannel catheter of Bertolero et al. so as to give the normally soft and pliable catheter enough rigidity to be manipulated within the heart from a position outside of the heart.

Claim 20 lacks novelty under PCT Article 33(2) as being anticipated by Thomas (US 5,342,383).

Thomas discloses a soft tip obturator (20) with a tip (26) which can be any length desired. The outer diameter of the obturator can be any desired size, but preferably 6 or 7 French.

---------- NEW CITATIONS ----------

US 5,342,383 (THOMAS) 30 August 1994, see Column 4, lines 3-15.

FOR THE PURPOSES OF INFORMATION ONLY

Codes used to identify States party to the PCT on the front pages of pamphlets publishing international applications under the PCT.

AL	Albania	**ES**	Spain	**LS**	Lesotho	**SI**	Slovenia
AM	Armenia	**FI**	Finland	**LT**	Lithuania	**SK**	Slovakia
AT	Austria	**FR**	France	**LU**	Luxembourg	**SN**	Senegal
AU	Australia	**GA**	Gabon	**LV**	Latvia	**SZ**	Swaziland
AZ	Azerbaijan	**GB**	United Kingdom	**MC**	Monaco	**TD**	Chad
BA	Bosnia and Herzegovina	**GE**	Georgia	**MD**	Republic of Moldova	**TG**	Togo
BB	Barbados	**GH**	Ghana	**MG**	Madagascar	**TJ**	Tajikistan
BE	Belgium	**GN**	Guinea	**MK**	The former Yugoslav Republic of Macedonia	**TM**	Turkmenistan
BF	Burkina Faso	**GR**	Greece			**TR**	Turkey
BG	Bulgaria	**HU**	Hungary	**ML**	Mali	**TT**	Trinidad and Tobago
BJ	Benin	**IE**	Ireland	**MN**	Mongolia	**UA**	Ukraine
BR	Brazil	**IL**	Israel	**MR**	Mauritania	**UG**	Uganda
BY	Belarus	**IS**	Iceland	**MW**	Malawi	**US**	United States of America
CA	Canada	**IT**	Italy	**MX**	Mexico	**UZ**	Uzbekistan
CF	Central African Republic	**JP**	Japan	**NE**	Niger	**VN**	Viet Nam
CG	Congo	**KE**	Kenya	**NL**	Netherlands	**YU**	Yugoslavia
CH	Switzerland	**KG**	Kyrgyzstan	**NO**	Norway	**ZW**	Zimbabwe
CI	Côte d'Ivoire	**KP**	Democratic People's Republic of Korea	**NZ**	New Zealand		
CM	Cameroon			**PL**	Poland		
CN	China	**KR**	Republic of Korea	**PT**	Portugal		
CU	Cuba	**KZ**	Kazakstan	**RO**	Romania		
CZ	Czech Republic	**LC**	Saint Lucia	**RU**	Russian Federation		
DE	Germany	**LI**	Liechtenstein	**SD**	Sudan		
DK	Denmark	**LK**	Sri Lanka	**SE**	Sweden		
EE	Estonia	**LR**	Liberia	**SG**	Singapore		

PATENT COOPERATION TREATY

PCT

INTERNATIONAL SEARCH REPORT

(PCT Article 18 and Rules 43 and 44)

Applicant's or agent's file reference	**FOR FURTHER ACTION** see Notification of Transmittal of International Search Report (Form PCT/ISA/220) as well as, where applicable, item 5 below.	
ESTC004/01WO		
International application No.	International filing date *(day/month/year)*	(Earliest) Priority Date *(day/month/year)*
PCT/US 00/ 04374	18/02/2000	19/02/1999
Applicant		
ENDOSCOPIC TECHNOLOGIES, INC. et al.		

This International Search Report has been prepared by this International Searching Authority and is transmitted to the applicant according to Article 18. A copy is being transmitted to the International Bureau.

This International Search Report consists of a total of 4 sheets.

☐ It is also accompanied by a copy of each prior art document cited in this report.

1. **Basis of the report**

   a. With regard to the **language**, the international search was carried out on the basis of the international application in the language in which it was filed, unless otherwise indicated under this item.

   ☐ the international search was carried out on the basis of a translation of the international application furnished to this Authority (Rule 23.1(b)).

   b. With regard to any **nucleotide and/or amino acid sequence** disclosed in the international application, the international search was carried out on the basis of the sequence listing :

   ☐ contained in the international application in written form.

   ☐ filed together with the international application in computer readable form.

   ☐ furnished subsequently to this Authority in written form.

   ☐ furnished subsequently to this Authority in computer readble form.

   ☐ the statement that the subsequently furnished written sequence listing does not go beyond the disclosure in the international application as filed has been furnished.

   ☐ the statement that the information recorded in computer readable form is identical to the written sequence listing has been furnished

2. ☒ **Certain claims were found unsearchable** (See Box I).

3. ☒ **Unity of invention is lacking** (see Box II).

4. With regard to the **title,**

   ☒ the text is approved as submitted by the applicant.

   ☐ the text has been established by this Authority to read as follows:

5. With regard to the **abstract,**

   ☒ the text is approved as submitted by the applicant.

   ☐ the text has been established, according to Rule 38.2(b), by this Authority as it appears in Box III. The applicant may, within one month from the date of mailing of this international search report, submit comments to this Authority.

6. The figure of the **drawings** to be published with the abstract is Figure No. 4

   ☐ as suggested by the applicant.

   ☒ because the applicant failed to suggest a figure.

   ☐ because this figure better characterizes the invention.

   ☐ None of the figures.

INTERNATIONAL SEARCH REPORT

International application No.
PCT/US 00/04374

Box I Observations where certain claims were found unsearchable (Continuation of item 1 of first sheet)

This International Search Report has not been established in respect of certain claims under Article 17(2)(a) for the following reasons:

1. [X] Claims Nos.: 15-17
because they relate to subject matter not required to be searched by this Authority, namely:

Rule 39.1(iv) PCT - Method for treatment of the human or animal body by surgery

2. [ ] Claims Nos.:
because they relate to parts of the International Application that do not comply with the prescribed requirements to such an extent that no meaningful International Search can be carried out, specifically:

3. [ ] Claims Nos.:
because they are dependent claims and are not drafted in accordance with the second and third sentences of Rule 6.4(a).

Box II Observations where unity of invention is lacking (Continuation of item 2 of first sheet)

This International Searching Authority found multiple inventions in this international application, as follows:

see additional sheet

1. [ ] As all required additional search fees were timely paid by the applicant, this International Search Report covers all searchable claims.

2. [ ] As all searchable claims could be searched without effort justifying an additional fee, this Authority did not invite payment of any additional fee.

3. [ ] As only some of the required additional search fees were timely paid by the applicant, this International Search Report covers only those claims for which fees were paid, specifically claims Nos.:

4. [X] No required additional search fees were timely paid by the applicant. Consequently, this International Search Report is restricted to the invention first mentioned in the claims; it is covered by claims Nos.:

1-14,18,19

Remark on Protest

[ ] The additional search fees were accompanied by the applicant's protest.

[ ] No protest accompanied the payment of additional search fees.

FURTHER INFORMATION CONTINUED FROM PCT/ISA/ 210

This International Searching Authority found multiple (groups of) inventions in this international application, as follows:

1. Claims: 1-14,18,19

A multichannel catheter for delivering extracorporeal blood comprising a central, first channel closed at the distal end, a second channel open at the distal end, a plurality of openings communicating with said first channel, an inflatable bladder, a third channel and a solid flexible shaft slidably engageable into said first channel.

2. Claim : 20

An obturator which comprises a shaft made of medical grade polymeric material having a length of 40-120 cm, a diameter of less than 28.2 French, a Durometer of about 40A to 90A and having a design to snugly and slidingly fit into a blood flow catheter to block the flow of blood through the channel.

INTERNATIONAL SEARCH REPORT

International Application No
PCT/US 00/04374

A. CLASSIFICATION OF SUBJECT MATTER
IPC 7 A61M25/10

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)
IPC 7 A61M

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practical, search terms used)
EPO-Internal, WPI Data, PAJ

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category °	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
Y	US 5 226 427 A (BUCKBERG GERALD D ET AL) 13 July 1993 (1993-07-13) column 4, line 33 -column 5, line 29; figures	1-14,18, 19
Y	US 5 807 328 A (BRISCOE RODERICK E) 15 September 1998 (1998-09-15) column 5, line 42 - line 59; figures	1-14,18, 19
Y	US 5 868 703 A (BERTOLERO RAYMOND S ET AL) 9 February 1999 (1999-02-09) cited in the application the whole document	1-14,18, 19
A	US 5 755 687 A (DONLON BRIAN S) 26 May 1998 (1998-05-26) column 4, line 18 - line 65; figures	1,18,19

☐ Further documents are listed in the continuation of box C.

☒ Patent family members are listed in annex.

° Special categories of cited documents :

"A" document defining the general state of the art which is not considered to be of particular relevance

"E" earlier document but published on or after the international filing date

"L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)

"O" document referring to an oral disclosure, use, exhibition or other means

"P" document published prior to the international filing date but later than the priority date claimed

"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention

"X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone

"Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art.

"&" document member of the same patent family

Date of the actual completion of the international search	Date of mailing of the international search report
26 July 2000	06. 11. 2000

Name and mailing address of the ISA	Authorized officer
European Patent Office, P.B. 5818 Patentlaan 2 NL - 2280 HV Rijswijk Tel. (+31-70) 340-2040, Tx. 31 651 epo nl, Fax: (+31-70) 340-3016	KOUSOURETAS, I

1

Form PCT/ISA/210 (second sheet) (July 1992)

INTERNATIONAL SEARCH REPORT

Information on patent family members

International Application No
PCT/US 00/04374

Patent document cited in search report	Publication date	Patent family member(s)	Publication date
US 5226427 A	13-07-1993	US 5021045 A	04-06-1991
		AU 633824 B	11-02-1993
		AU 3551189 A	24-11-1989
		EP 0411039 A	06-02-1991
		JP 3503966 T	05-09-1991
		NO 904476 A	17-12-1990
		WO 8910155 A	02-11-1989
		US 5423745 A	13-06-1995
US 5807328 A	15-09-1998	NONE	
US 5868703 A	09-02-1999	AU 2462597 A	29-10-1997
		EP 0892652 A	27-01-1999
		WO 9737716 A	16-10-1997
		AU 2451197 A	29-10-1997
		AU 2665297 A	29-10-1997
		AU 2666097 A	29-10-1997
		WO 9737596 A	16-10-1997
		WO 9737597 A	16-10-1997
		WO 9737581 A	16-10-1997
US 5755687 A	26-05-1998	AU 7099798 A	22-10-1998
		EP 0912212 A	06-05-1999
		US 6056723 A	02-05-2000
		WO 9843696 A	08-10-1998

PCT WORLD INTELLECTUAL PROPERTY ORGANIZATION
International Bureau

INTERNATIONAL APPLICATION PUBLISHED UNDER THE PATENT COOPERATION TREATY (PCT)

(51) International Patent Classification 7 : A61M 25/10

A2

(11) International Publication Number: WO 00/48659

(43) International Publication Date: 24 August 2000 (24.08.00)

(21) International Application Number: PCT/US00/04374

(22) International Filing Date: 18 February 2000 (18.02.00)

(30) Priority Data:
60/120,038 19 February 1999 (19.02.99) US

(71) Applicant *(for all designated States except US)*: ENDOSCOPIC TECHNOLOGIES, INC. [US/US]; Suite 100, 4115 Blackhawk Plaza Circle, Danville, CA 94506 (US).

(72) Inventors; and
(75) Inventors/Applicants *(for US only)*: BERTOLERO, Arthur, A. [US/US]; 155 Sunhaven Road, Danville, CA 94506 (US). BERTOLERO, Raymond, S. [US/US]; 130 Windover, Danville, CA 94506 (US). RIEBMAN, Jerome, B. [US/US]; 1291 Brookings Lane, Sunnyvale, CA 94087 (US).

(74) Agents: MORAN, Tom, M.; Cooley Godward LLP, Five Palo Alto Square, 3000 El Camino Real, Palo Alto, CA 94306-2155 (US) et al.

(81) Designated States: AE, AL, AM, AT, AU, AZ, BA, BB, BG, BR, BY, CA, CH, CN, CR, CU, CZ, DE, DK, DM, EE, ES, FI, GB, GD, GE, GH, GM, HR, HU, ID, IL, IN, IS, JP, KE, KG, KP, KR, KZ, LC, LK, LR, LS, LT, LU, LV, MA, MD, MG, MK, MN, MW, MX, NO, NZ, PL, PT, RO, RU, SD, SE, SG, SI, SK, SL, TJ, TM, TR, TT, TZ, UA, UG, US, UZ, VN, YU, ZA, ZW, ARIPO patent (GH, GM, KE, LS, MW, SD, SL, SZ, TZ, UG, ZW), Eurasian patent (AM, AZ, BY, KG, KZ, MD, RU, TJ, TM), European patent (AT, BE, CH, CY, DE, DK, ES, FI, FR, GB, GR, IE, IT, LU, MC, NL, PT, SE), OAPI patent (BF, BJ, CF, CG, CI, CM, GA, GN, GW, ML, MR, NE, SN, TD, TG).

Published
Without international search report and to be republished upon receipt of that report.

(54) Title: MULTICHANNEL CATHETER WITH OBTURATOR

(57) Abstract

This invention is a multichannel catheter for extracorporeal circulation of blood to a patient undergoing cardiovascular treatments or surgery. The catheter has three independent channels, an obturator and an expandable balloon at one end of the catheter. The first channel is the largest and is of a size that allows for delivery of blood through outlet parts in the wall of the first channel to a patient in an amount sufficient to maintain the patient's metabolism and perfusion throughout the treatment or surgery. The obturator is longitudinally insertable into the first channel. A second channel, smaller than the first, is integrated into the wall of the first channel, and is suitable for delivering a biologically active fluid (e.g., for cardioplegia) to the heart and/or venting the left heart. A third channel, also smaller than the first, is integrated into the wall of the first channel, and suitable for delivering a fluid to the balloon for its expansion when positioned in the ascending aorta to occlude the flow of blood to the heart. The catheter provides an improved means of preparing for or performing cardiovascular surgery on a patient using a cardiopulmonary machine for extracorporeal circulation of blood. The catheter is particularly useful for cardiac surgery.

FOR THE PURPOSES OF INFORMATION ONLY

Codes used to identify States party to the PCT on the front pages of pamphlets publishing international applications under the PCT.

AL	Albania	ES	Spain	LS	Lesotho	SI	Slovenia
AM	Armenia	FI	Finland	LT	Lithuania	SK	Slovakia
AT	Austria	FR	France	LU	Luxembourg	SN	Senegal
AU	Australia	GA	Gabon	LV	Latvia	SZ	Swaziland
AZ	Azerbaijan	GB	United Kingdom	MC	Monaco	TD	Chad
BA	Bosnia and Herzegovina	GE	Georgia	MD	Republic of Moldova	TG	Togo
BB	Barbados	GH	Ghana	MG	Madagascar	TJ	Tajikistan
BE	Belgium	GN	Guinea	MK	The former Yugoslav Republic of Macedonia	TM	Turkmenistan
BF	Burkina Faso	GR	Greece			TR	Turkey
BG	Bulgaria	HU	Hungary	ML	Mali	TT	Trinidad and Tobago
BJ	Benin	IE	Ireland	MN	Mongolia	UA	Ukraine
BR	Brazil	IL	Israel	MR	Mauritania	UG	Uganda
BY	Belarus	IS	Iceland	MW	Malawi	US	United States of America
CA	Canada	IT	Italy	MX	Mexico	UZ	Uzbekistan
CF	Central African Republic	JP	Japan	NE	Niger	VN	Viet Nam
CG	Congo	KE	Kenya	NL	Netherlands	YU	Yugoslavia
CH	Switzerland	KG	Kyrgyzstan	NO	Norway	ZW	Zimbabwe
CI	Côte d'Ivoire	KP	Democratic People's Republic of Korea	NZ	New Zealand		
CM	Cameroon			PL	Poland		
CN	China	KR	Republic of Korea	PT	Portugal		
CU	Cuba	KZ	Kazakstan	RO	Romania		
CZ	Czech Republic	LC	Saint Lucia	RU	Russian Federation		
DE	Germany	LI	Liechtenstein	SD	Sudan		
DK	Denmark	LK	Sri Lanka	SE	Sweden		
EE	Estonia	LR	Liberia	SG	Singapore		

MULTICHANNEL CATHETER WITH OBTURATOR

BACKGROUND OF THE INVENTION

RELATED U.S. APPLICATION DATA

This application claims the benefit of U.S. Provisional Application Serial No. 60/120,038, filed February 19, 1999.

FIELD OF THE INVENTION

This invention relates to a multichannel catheter, i.e. a perfusion cannula, useful in arterial perfusion of the aorta, generally via a femoral artery for use in conjunction with cardiovascular examinations, treatments and surgery. It also relates to methods for making and using such a catheter.

BACKGROUND OF THE INVENTION

To better understand the background and problems faced by those of skill in this area of technology it is useful to understand the basic workings of the heart and circulatory system. The following discussion refers to schematics of the heart shown in FIGS. 1 and 2. The human heart is a muscular pump having four separate cavities and a series of valves allowing blood to pass in one direction only. Mammals, including humans, have a double circulatory system. Blood that has released oxygen to the tissues **9** and **14** and has absorbed carbon dioxide from them (venous blood) is returned to the heart through the superior and the inferior venae cavae **11** and **10**. This blood enters the right auricle **3**, whose contractions cause the blood to pass through the tricuspid valve **16** in the right ventricle **1**. The

contractions of the right ventricle pass the blood through the pulmonary semilunar valves **17** and along the two pulmonary arteries **5** into the lungs **6**. In the lungs, the blood is oxygenated and returns to the heart through the pulmonary veins **7** and thus enters the left auricle **4**. This chamber contracts and passes the blood through the bicuspid, or mitral, valve **15** into the left ventricle **2**, whose contractions force the blood through the aortic semilunar valve **18** into the aorta **12** and **13**, which is the biggest artery of the body and to other parts of the body through, *i.a.*, the great arteries **8**. Thus the right side of the heart serves mainly to pump deoxygenated blood through the lungs, while the left side pumps oxygenated blood throughout the rest of the body. This is represented as a flow schematic in FIG. 2, where similar numbers refer to similar parts of the heart. The heart varies the output by varying the volume of blood admitted into the ventricles each time the latter are filled and also by varying the rate of contraction (faster or slower heartbeat). The left side of the heart (left auricle and ventricle) has to circulate the blood through all parts of the body, except the lungs, and has thicker and more strongly muscular walls than the right side, which has to perform the pulmonary blood circulation only. For proper functioning, the left side and the right side must be accurately interadjusted, both with regard to the contraction rate of the respective chambers and with regard to the output of blood. When functional disorders of the heart occur, it may be necessary to examine the heart to determine the problem and possibly perform surgery or provide treatment.

In performing examinations or treatments of a subject's heart, or performing surgery on the heart, it is often necessary to reduce the rate at which it normally beats or stop its beating completely. This allows a physician to observe, or operate on, the heart more easily. However, by reducing or stopping the heart rate (i.e. cardioplegia), blood will not be adequately circulated to the rest of the body. Thus, it is generally necessary to circulate the blood using some type of extracorporeal blood circulating means that regularly circulates oxygen-rich blood through the arteries, collects oxygen-depleted blood returning through the veins, enriches the oxygen-depleted blood with additional oxygen, then again circulates the oxygen-rich blood.

The types of examinations, treatments and operations that require some degree of cardioplegia or drug delivery and extracorporeal blood circulation include open heart surgery and less-invasive heart surgery to perform single or multiple coronary artery bypass operations, correct malfunctioning valves, etc. Others include, but are not limited to,

myocardial revascularization, balloon angioplasty, correction of congenital defects, surgery of the thoracic aorta and great vessels, and neurosurgical procedures.

The extracorporeal blood circulation generally requires the use of some type of heart-lung machine, i.e. a cardiopulmonary machine. This has the threefold function of keeping the replacement blood in circulation by means of a pumping system, of enriching with fresh oxygen the blood of low oxygen content coming from the patient's body, and regulation of patient temperature. The system shown in FIG. 3 diagrammatically describes the manner in which such a machine works.

The venous blood, before it enters the right auricle of the heart is diverted into plastic tubes **20**, generally by gravity flow. The tubes are positioned to receive the blood from the superior and inferior venae cavae (shown as **11** and **10** in FIG. 1). This blood, which has circulated through the body and consequently has a low oxygen content is collected in a reservoir **21**. A blood pump **22** is used to pump the blood through a heat exchanger **23** and artificial lung **24**. The heat exchanger **23** and artificial lung **24** may be one of several designs to regulate blood temperature and increase the oxygen content of the blood. Modern designs use advanced membrane technology to achieve the oxygenation, which is similar to the way red blood cells absorb oxygen from the human lung. The oxygenated blood then passes through a filter **25** and is returned to the patient. Losses of blood occurring during the course of the operation are compensated by an additional blood reservoir **26**. Collected blood is passed through a defoamer **27** and is likewise passed to the reservoir **21**, heat exchanger **23** and artificial lung **24**. Before starting the cardiopulmonary bypass machine the extracorporeal circuit is filled with one or two liters of saline solution. In circulating the oxygenated blood to the body from filter **25**, it can be pumped through a catheter **28** by inserting the catheter into the aorta or one of its major branches and pumping the blood through the catheter. However, when the heart is to be operated on, it must be free of blood and sometimes the heart beat must be reduced or stopped completely. Referring again to FIG. 1, blood is prevented from entering the heart by blocking the ascending aorta **12** near the semilunar valve **18** while at the same time preventing blood from entering the right auricle **3** by withdrawing blood through the superior vena cavae **11** and inferior vena cavae **10**. Blocking the ascending aorta may be achieved by clamping or preferably by balloon blockage. At the same time that blood is prevented from flowing through the heart, a cardioplegia solution is administered locally to the heart to arrest the heart. Thus, there is a need for a device that allows a heart specialist to locally administer cardioplegia to the heart,

block the flow of blood to the heart, while at the same time circulating oxygenated blood to the patient's body, particularly through the great arteries 8 in FIG. 1, to ensure all limbs and tissues remain undamaged during the heart examination or operation. Several devices are described in the literature to address the need for an appropriate device. One example is disclosed in U.S. Patent number 5,312,344 issued 17 May 1994 to Grinfeld et al.

Another example can be seen in U.S. Patent number 5,433,700, issued 18 July 1995 to Peters. This patent describes a process for inducing cardioplegic arrest of a heart which comprises maintaining the patient's systemic circulation by peripheral cardiopulmonary bypass, occluding the ascending aorta through a percutaneously placed arterial balloon catheter, venting the left side of the heart, and introducing a cardioplegia agent into the coronary circulation. As part of the disclosure a multichannel catheter is disclosed which provides channels for the cardioplegia solution, a fluid transportation to inflate the balloon, a lumina for instrumentation and a separate catheter to deliver oxygenated blood to the body.

Another example of a device is found in U.S. Patent number 5,478,309, issued 26 December 1995 to Sweezer et al. This is a rather complex device and system of venous perfusion and arterial perfusion catheters for use in obtaining total cardiopulmonary bypass support and isolation of the heart during the performance of heart surgery.

Another device is described in U.S. Patent number 5,458,574, issued 17 October 1995 to Machold et al. It shows a multichannel catheter which has channels for fluid to blow up balloons for blocking the aorta, a channel for cardioplegia solution and a channel for instruments for examining the heart.

Still another patent, U.S. Patent number 5,452,733, issued 26 September 1995 to Sterman et al.

Another patent application, PCT/US 94/09938, having international publication number WO95/08364, filed 1 September 1994 in the name of Evard et al., describes an endovascular system for arresting the heart. PCT International Application number PCT/US 94/12986, published as Publication number WO95/15192, filed 10 November 1994, in the name of Stevens et al., provides a description of a partitioning device that is coupled to an arterial bypass cannula. U.S. Patent number 5,868,703, issued 9 February 1999 (the '703 patent), discloses an improved device that aids a surgeon in performing open or closed heart surgery.

However, the design of the improved device has led to certain problems in the smooth operation of the device. For example, the design of the '703 device requires the presence of blood outlets strategically located along a portion of the multichannel catheter. When the distal tip of the device, which carries the balloon, is inserted into a femoral artery through a percutaneous opening, some of the blood portal will be located inside the artery (interior portals) while others will be temporarily located outside the artery (exterior portals). For a short period of time, blood, which flows in the artery will enter the catheter through the interior blood portal then exit through the exterior portals. This problem is solved by this invention through using an internal, slidable obturator in the blood flow channel to block both the interior & exterior portals during insertion of the multichannel catheter until all the portals are located within the artery. The obturator is then withdrawn to allow blood from a cardiopulmonary machine to be pumped through the blood flow channel of the multichannel catheter.

SUMMARY OF THE INVENTION

One aspect of this invention is a multichannel catheter useful for delivering extracorporeal blood to a mammal (particularly a human) by insertion into a blood vessel of the mammal. The catheter has a defined length with distal and proximal ends. The catheter has a central, first channel defined by a surrounding wall extending substantially the length of the catheter, which channel is closed at its distal end. A second channel (i) extends the entire length of the catheter parallel to the first channel but independent thereof, (ii) is integrated into the wall of the first channel, and (iii) is open at its distal end. In the wall of the catheter is at least one opening for the flow of blood communicating only with said first channel. Integrated into the distal end of the catheter between the opening for the flow of blood and the second channel distal opening is an inflatable bladder. A third channel (i) extends substantially the length of the catheter integrated into the wall of the first channel; (ii) being parallel to the first and second channels but independent thereof, and (iii) has a distal opening in fluid communication with the interior of the inflatable bladder. A solid flexible shaft slidably engageable into the first channel extends substantially the length of the first channel.

Still another aspect of this invention is a process for preparing for cardiovascular surgery in a mammal. The process comprises

(A) inserting into a femoral artery of the mammal the distal end of the catheter described above (and in greater detail hereinafter) with the flexible shaft slidingly engaged in the first channel to prevent backflow of blood,

(B) positioning the catheter so that the inflatable bladder is located in the ascending aorta, and

(C) removing the flexible shaft from the first channel to allow the first channel to be connected to a cardiopulmonary machine to pump blood into the first channel at the proximal end of the first channel. Other steps are also taken, as discussed hereinafter.

Another aspect of this invention is a process for preparing a multichannel catheter. The process comprises:

(A) extrusion molding a catheter having distal and proximal ends wherein the catheter comprises

(1) a central, first channel extending substantially the length of the catheter and being defined by the wall of the catheter;

(2) a second channel extending the entire length of the catheter, being integrated into the wall of the first channel;

(3) a third channel extending substantially the length of the catheter parallel to the first and second channels but independent thereof and being integrated into the wall of the first channel and spaced from the second channel,

(B) integrating an inflatable bladder into the distal end of the catheter so that a distal outlet of the third channel communicates with the interior of the bladder; and

(C) slidingly inserting a flexible, shaft into the central first channel, wherein the shaft has a handle for positioning the shaft within the central channel.

Alternatively, the invention can be described as a multichannel catheter useful for extracorporeal circulation of the blood to a patient undergoing cardiovascular surgery. The catheter comprises at least three independent channels and an expandable balloon at one end of the catheter. The catheter has a first channel of a size to permit delivery of an amount of blood to the patient that is sufficient to support the patient metabolism and perfusion throughout the surgery. The first channel has at least one outlet port along at least a portion of the wall of the channel. A second channel, narrower than the first channel and integrated into the wall of the first channel, is present for at least for delivering cardioplegia solution to the heart or for venting the left heart. A third channel, also narrower than the first channel and integrated into the wall of the first channel, is suitable for delivery of fluid to the balloon for expansion when positioned in the ascending aorta to occlude the flow of blood. A flexible shaft is slidably inserted into the first channel of the catheter and has a handle located at the proximal end of the shaft for slidably positioning the shaft along the length of the first channel to block at least one outlet port in the wall of the catheter.

Another aspect of this invention is an obturator useful for slidably inserting into a blood-flow catheter, which oburator comprises a flexible shaft made of medical grade polymeric materials having a length of about 40 cm to about 120 cm, having a cross-sectional diameter of less than about 28.2 French, having a Durometer rating of about 40A to about 90A, and having a cross-sectional design to snugly and slidingly fit into a blood flow catheter channel to block the flow of blood through the channel.

Other aspects of the invention will be apparent to one of skill in the art upon reading the following specification and claims.

DESCRIPTION OF THE DRAWINGS

In the accompanying drawings:

Figure 1 is a diagram of a mammal's heart and circulatory system showing the approximate configuration of the heart.

Figure 2 is a schematic representative of how a mammalian heart works without regard to its configuration.

Figure 3 is a schematic representation of how a cardiopulmonary machine works.

Figure 4 is a longitudinal cross-section view of the proximal portion of the balloon catheter of the invention showing the interrelationship between the major parts of the proximal portion.

Figure 5A is a perpendicular cross-section taken along line 5--5 of Figure 4.

Figure 5B shows a closely related configuration taken along line 5--5 of Figure 4.

Figure 5C shows a slight modification of the cross-section taken along the line 5--5 of Figure 4.

Figures 5D and 5E show a slightly different modification of the cross-section taken along the line 5--5 of Figure 4.

Figures 6A and 6B show a cross-section of the longitudinal axis of a slightly different configuration of the proximal portion of the multi-lumen catheter of this invention.

Figure 7 shows a perpendicular cross-section taken along lines 5--5 of Figure 4 and shows the size relationships between the various parts of the multi-channel catheter of this invention.

Figure 8 shows a cardiopulmonary system using the catheter of this invention.

Figure 9 is a representation of a preferred aspect of the balloon catheter of the invention having an internal obturation.

Figure 10A shows a preferred aspect of the balloon catheter of the invention having an internal obturation.

Figure 10B shows a magnified view of a portion of 10A.

Figure 11 shows a partial view of the balloon catheter of the invention having positioning indicators located along the central passageway of the device.

Figures 12A and 12B show a full length view of the obturator useful in this invention and a perpendicular cross-section taken along lines J--J of the full length obturator and shows the size relationships between the various parts of the obturator.

Figure 13 is a schematic representation of how the catheter of the invention works in a mammal's heart and circulatory system.

Figures 14A, 14B and 14C show cross-sectional views of the distal portion of the balloon catheter of this invention.

Figure 15 shows the balloon catheter of this invention properly positioned within the ascending aorta.

Figure 16 shows an alternative view of a catheter that is inserted through the ascending aorta.

DETAILED DESCRIPTION OF PRESENTLY PREFERRED EMBODIMENTS

This invention is based on the discovery that an obturator, that is, a device used to block a longitudinal passageway, can be used to prevent blood leakage in certain blood delivery catheters. The invention has several aspects: (1) a multichannel aortic balloon catheter in combination with an obturator; (2) the design of the obturator itself; (3) a process for using the combination of (1), above; and (4) a process for making the combination . Other aspects will be apparent to one of skill in the art upon further reading of the details of this specification.

Multi-Channel Catheter and Obturator

One aspect of this invention is a multichannel catheter (that includes an obturator) that is useful for delivering extracorporeal blood to a mammal (especially a human) in need thereof. The catheter allows a physician to deliver extracorporeal blood to the patient, occlude the flow of blood at the ascending aorta, deliver cardioplegia fluid to the heart, vent the left heart, and optionally monitor pressure and observe the internal workings of the aorta region.

The multichannel catheter is of a diameter size to be inserted into the aorta or one of its major branches (e.g. a femoral artery) and used in open chest surgery or in less invasive surgery. Alternatively, the catheter is used in open chest surgery and inserted by cannulation at the aorta or through one of the great arteries, e.g., the brachiocephalic artery. The design

of the blood flow configuration will depend on where and how the catheter is to be inserted, as discussed hereinafter.

In general, the multichannel catheter of this invention comprises at least 3 passageways, with a large, central passageway to maximize the flow of oxygenated blood from a cardiopulmonary machine. It is desirable to maximize the flow of blood through the large channel while minimizing the outside diameter of the catheter and thus provide adequate systemic extracorporeal blood flow for the vast majority of patients in which the catheter is used. Of the available longitudinal passage space in the catheter of this invention, generally at least about 50% is allocated to this large passageway to maximize the flow. Preferably about 70% and more preferably about 90% of the available passageway volume, is used for the flow of perfused blood to the arterial side of a patient in need of supplementary, extracorporeal blood circulation. The other channels, at least two, comprise the remainder of the available volume (i.e., about 10%-50%) with each channel integrated into the wall of the large central passageway. Generally, the available volume is determined by calculating the area of a cross-section of each longitudinal passageway and multiplying by the length. Since the length is about the same in each case, the relative volume for each channel will be directly proportional to the cross-sectional area of each passageway.

More specifically and with reference to Figure 12A, the multichannel catheter has distal and proximal ends that correspond approximately to the distal and proximal ends of the shaft **134** of the obturator as shown in Figure 12A. The long distal portion **130** of the shaft of the obturator of Figure 12A fits into the large lumen for the flow of blood and has a blunt or rounded end **136**. The obturator has a handle **138**, allowing the physician or assistant assisting in the operation to have control of the obturator. A cross section of the obturator J-J is shown in Figure 12B. The obturator has two channels **140**, that corresponds to the other two channels of the catheter, as discussed hereinafter. The large central, first channel, (i.e., a passageway or lumen) of the multichannel catheter of this invention, is defined by a surrounding wall that extends substantially the length of the catheter, is closed at its distal end, and has at least one outflow opening for extracorporeal blow flow along the length of the catheter, as discussed in greater detail hereinafter. The catheter has at least second and third channels, each of which extends substantially the length of the catheter, parallel to said first channel but independent thereof. Together, these additional channels (2, 3 or more) comprise not more than about fifty percent of the available internal channel volume of the catheter and are preferably integrated into the wall of the first channel. In a three-channel configuration,

the second channel (generally the larger of the two smaller channels) is open at its distal end, while the third channel's distal end is in communication with the interior of an inflatable bladder, *i.e.*, a balloon. The catheter further preferably has a plurality of openings in the wall of the first channel extending part of the length of the first channel, some near the distal end of said catheter communicating only with the first channel. These openings are ports or outlets for blood from a cardiopulmonary machine. The balloon is integrated into the distal end of the catheter between the first channel blood outflow openings and second channel's distal opening. The blood flow openings are said to be "upstream" or proximal of the balloon, while the distal opening of the second channel is said to be "downstream" or distal of the balloon. The interior of the inflatable means communicates with the distal end of the third channel through an opening in the wall of the catheter.

As discussed, the catheter can be a disposable, flexible polymeric (e.g. polyurethane) tube with at least three lumens with an inflatable balloon, *e.g.* polyurethane at the distal end of the cannula. The catheter is combined with the obturator so that the shaft of the obturator is snugly situated inside the first channel and slidably positioned along the length of the first channel. The outside diameter of the cannula is suitable for insertion into a femoral artery. The catheter's central lumen or channel is for the delivery of arterial blood through multiple distal outlets all upstream (relative to blood flow from a cardiopulmonary machine) of the distal balloon, a lumen that communicates with the aorta in the area of the aortic root for delivery of cardioplegic solution (and left ventricular venting, if desired), and a small lumen for control of the distal balloon. Radio-opaque balloon indicator and insertion depth marks aid in positioning the device into a patient. The catheter is preferably a non-pryogenic, single use, sterile device, which is packaged individually.

This device is intended for use in arterial perfusion of the aorta, via a femoral artery, in cardiovascular surgery procedures requiring extracorporeal cardiopulmonary bypass (CPB) with required blood flow rates of one to five Liters per Minute. Generally, the Maximum Recommended Blood Flow Rate is five Liters per Minute.

Turning now to FIG. 4, one can see a detailed representation of the catheter of this invention which is a cross-sectional view of the length of the catheter without an obturator in the blood flow lumen. A cross section of the catheter **100** is shown generally as having a proximal end **31** and a distal end **33**. The large central first channel **34** is defined by the wall **32** of the catheter. The second channel **36** and the third channel **38** are shown as being integrated into the wall of the first large channel. The second and third channels are

integrated with the wall **32** of the first channel **34** and are shown as having an interior wall portion **41** defining the smaller second and third channels. This can be seen more clearly in Figures 6A and 6B. In Figures 6A and 6B one can see a cross section of the catheter **100** having a large central lumen **34** and smaller lumens **36** and **38** that are integrated into the wall **32**. A blood outflow portal **40** is shown in part in Figure 6B.

In Figure 4, toward the distal end **33** of the catheter **100** are located openings **40** that are outlet ports for the fluid passing through the channel **34**. In use, that fluid will be extra-corporeal blood that is circulated to the arterial side of a patient in need of such extra-corporeal circulation. As will be discussed in greater detail, hereinafter, the catheter of this invention is preferably designed to be inserted into a femoral artery of a human patient and advanced sufficiently so that the distal end is positioned in the ascending aorta. Thus, the catheter, and preferably the obturator, must be flexible enough to readily bend at its distal end as shown in Figures 13 and 15. The catheter, and preferably the obturator are designed to minimize kinking to avoid reduced fluid flow through the passageways **34**, **36** and **38** as shown in FIG. 4. The openings **40** as shown in Figure 15, are located on the proximal side (i.e. upstream) of the inflatable bladder **42**. The openings **40** may be spread along the length of catheter as shown in Figures 8, 9 and 10A. Blood from the cardiopulmonary machine will flow in the direction of the arrow as shown in Figure 4 and out the blood outlet ports **40** along the length of the catheter with some flowing out of channel **34** near the great arteries. As shown in Figure 4, while some of the openings may be adjacent the balloon **42**, for example within about an inch of the proximal edge **44** of balloon **42**, the openings **40** are located such that they do not contribute to kinking of the catheter as it passes the aortic arch. Thus the openings **40** are located in the distal portion of the catheter so that when the catheter is positioned as shown in FIG. 8 the openings are in a region of the catheter that is relatively straight. A few of the openings may be located immediately adjacent the proximal side of the balloon **42** (e.g., within about an inch of the proximal edge **44** of the balloon **42**), while the majority will be along the distal 50% of the catheter.

Figure 16 shows a perspective view of a portion of blood delivery catheter **100** in combination with the obturator **2**. The view of Figure 16 is a perspective view with the obturator shown inside the channel **34** and is shown by dotted lines as the outline of the obturator. The blood delivery catheter is shown as having blood outlet ports shown as 40A-40D for blood to come out along the length of the catheter. Blockage of the ports is shown by the wavy lines **142**. This is shown in simplest form and will be explained in that manner.

In operation, if one wishes to deliver blood to an artery, one would enter the femoral artery, e.g. through a percutaneous opening, or cut down, and insert the distal end of the blood flow catheter/obturator combination. Once the catheter is inserted into the artery, it is moved up the artery to be positioned as desired so that the balloon is at the ascending aorta. One can see that if the obturator is not present on the inside of the blood flow catheter (from Figures 4, 9 or 10A), blood flowing in the artery would flow into cavity **34** and through a port nearest the distal tip out through other ports **40**. On the other hand, if the obturator is snugly positioned in the interior of the catheter in channel **34** and positioned as shown, and the distal tip **101** of the blood delivery catheter is inserted into the artery, blood will enter the lumen **34** through port 40A, but will not exit ports 40B-40D that are more proximal because the internal flow of the blood from the heart and artery would be blocked by the obturator. As the catheter is inserted further and further along into the femoral artery, the obturator can be withdrawn in the opposite direction of the arrow shown in Figure 4. Once all ports **40** are positioned so that they are inside the artery, the obturator can be withdrawn to a point designated as **12** in Figure 16, without having to worry about blood entering lumen **34** exiting outside of the body. Thus, the obturator is withdrawn as the catheter is inserted until it reaches a point where blood from a cardiopulmonary machine can be added to the internal blood flow lumen at its proximal end as will be discussed in more detail hereinafter.

It is important that the total outflow capacity of the outlet ports **40**, **40A-40D** (as shown in for example, Figures 4, 10A, 15, and 16) is greater than the inflow capacity of the blood flowing into the catheter. This will mean that total collective cross-sectional area of openings **40** will exceed the total cross-sectional area of channel **34**. Thus, to calculate the collective cross-sectional area of openings **40**, one determines the area of each opening and adds the area of each opening. Preferably the total area (i.e. outflow capacity) of the openings will exceed the cross-sectional area (i.e. inflow capacity) of channel **34** by at least a factor of 1.2. Having a factor of greater than about 2 is even more preferable. For example, if the radius of channel **34** is 2.5 mm, the cross-sectional area is 19.6 (2.5 x 2.5 x 3.14=19.6) and the total cross-sectional area of the openings **40** will be at least 23.6 (1.2 x 19.6=23.6), more preferably 39.2 (2 x 19.6=39.2). Preferably, each opening has a cross-sectional area of about 3-40 mm^2, preferably about 5 to about 20 mm^2. The total number of openings may be as few as three large openings up to about 20 or more openings of various shapes.

While the shape of the openings **40** may be of any appropriate shape for the outflow of blood, it is preferable that some, generally a majority of the openings are elongate in

shape. While the openings may be positioned in any configuration toward the distal end of the catheter, for example, the longitudinal axis of the elongate openings may be positioned substantially parallel to the length of the catheter or at a slight angle such that it forms a helical design or the length could be perpendicular to the length of the catheter. However, it is preferred that the elongate openings have the length of the opening substantially parallel to the length of the catheter. While at least one opening **40** in the wall will be present, the number of openings that can be present may vary from **2** to **20** or more but must be placed in a manner that the structural integrity of the catheter is maintained. By having elongate openings instead of circular openings the sheer stress on the blood is reduced by allowing the blood to flow out of the outlets more easily. In addition to the elongate openings located in the distal region of the catheter as shown in Figure 4, other openings may be located further upstream of the elongate openings **40**. Further designs may be seen in FIGS. 8, 9 and 10A. The design of the openings **40** may generally be that of an oval, a rectangle, a trapezoid or some similar elongated design. In general, they will be approximately one cm to about four cm, e.g. about 2.5 cm long with a width at the broadest portion of the opening no more than about 5 mm. The openings **40** are positioned toward the distal end of the largest channel so that when the catheter is positioned with the balloon **42** in the ascending aorta, the openings are near the great arteries so that blood can flow more freely to the great arteries to ensure the necessary oxygenation of tissues (i.e. perfusion) for the rest of the body. The outlet ports may be spread along about the distal 60% of the largest channel. By having a majority of (e.g., oval) openings and ensuring the outflow capacity exceeds the inflow capacity, the sheer stress on the blood passing through the first channel **34** will be significantly reduced. By having elongate openings at the distal end and maximizing the size of channel **34**, the flow rate through the large channel **34** may be up to six liters (L) per minute without having adverse affect on the blood due to too much shear stress on the red cells, platelets or white cells. Having elongate openings and proper outflow capacity, reduces the pressure drop between the proximal end where the catheter is attached to the cardiopulmonary machine and the exit at the openings **40**. Generally, the pressure drop will be under 300 millimeters of mercury and preferably under 200 millimeters of mercury. The pressure drop can be further reduced by having additional holes towards the proximal end of the catheter but preferably somewhere between the midpoint of the catheter and the distal end. This design is seen in FIG. 10A. As discussed before, the openings **40** will be positioned and constructed to minimize the chance of kinking when the catheter passes over the curve of the aortic arch and generally will be sufficiently proximal of the balloon **42** with the largest cross-section of

openings to be positioned in a section of the catheter that remains straight. While, a few (e.g., 2-4) small openings may be placed within about 2.5 cm proximal of the balloon **42**, the majority are about 7.5 cm to about 30 cm on the proximal side (i.e., upstream) of the balloon, depending on the catheter sizing for the patient.

In general, the maximum length of the multichannel catheter of this invention will be that length necessary to insert the catheter into the femoral artery of the patient and moving it up the artery to place the distal end having the balloon within the ascending aorta. Depending on the size of the patient, whether a child or an adult, the length may be from about 40 centimeters up to about 120 centimeters or more. Generally, the range will be about sixty to about one hundred centimeters with about eighty-five centimeters being an average length suitable for most people. The length will be significantly less when used in open-chest surgery with aortic insertion or brachiocephalic cannulation. The length of the associated obturator will be in the same range, but will be somewhat shorter in that the distal tip of the obturator will not necessarily have to extend to the distal tip of the catheter.

Turning to Figure 12A, one sees the length **144** of the obturator **146** which can be used in the combination of the invention. Generally, the length **144** of the obturator **146** will be sufficiently long so that it will be inserted into a multichannel catheter which will be positioned so that a balloon at the distal end of the catheter will block the ascending aorta between the brachiocephalic artery and the coronary ostia. While the obturator **146** may fit the entire length of the multichannel catheter to the end of the blood flow channel and thus may extend over the aortic arch, it will generally be sufficient to only extend to the second opening from the distal end of the multichannel catheter. The length of the obturator's distal end **130** will generally be from about 40 cm up to about 120 cm. The exact length of the obturator will depend on the size of the patient that is being operated upon, whether a child or an adult. Generally, the length of the obturator will be about 60 to about 100 centimeters with about 85 centimeters being an average length suitable for most people. The handle portion **138** of the obturator will be of a size that is large enough for the physician or assistant assisting in the operation to push the obturator in or pull it out. Generally, the length of the handle will be anywhere from about 3 to 15 centimeters. The obturator and the handle **138** may be extruded from one polymeric material or the handle may be bonded to the distal portion of the obturator through heat bonding or using an appropriate adhesive such as Dymax 19 1M. The material that can be used for the obturator is any material that is bio-compatible with a patient's blood, that is, it is physiologically acceptable and will not have an

adverse affect on the patient when used in the manner it is intended. The bio-compatible material for preparing the obturator will have to be of the nature that it will readily slide into and out of the lumen that is carrying the blood. Depending on what material the multichannel catheter lumen has in its lining, the preferred material will be a pulomeric substance that has a significant degree of flexibility. On the other hand, it will be not be so flexible that it is unable to easily be moved throughout the channel. A material that is particularly useful is low density polyethylene or hytrel. Other polymeric material that can be used includes polyvinylchloride (PVC) which has been plasticized using a plasticizer such as trioctyl trimellitate (TOTM) or di (2-ethyl-hexyl) phthalate (DEHP). Suitable PVC resin is available from Dow Chemical Corporation, Midland, Michigan, or the Polomer Technology Group (PTG) Inc., Emeryville, California. Other polymers that are useful include medical grade polyurethane, polysiloxane containing co-polymers which may be also referred to as surface modified additions (SMAs). These polymers may be blended with a base polymer before processing or coated on a blood contacting surface. When blended with the base polymer, the SMA will migrate to the polymer surface resulting in a high concentration of the SMA on that surface which has fewer adverse effects with the blood that contacts it. Other polymers may be apparent to those of ordinary skill upon further consideration of this invention.

It is advantageous to design the catheter so that the distal portion of the catheter that transcends the aortic arch has only the two smaller channels. Thus, the distal end of large channel **34** would not go around the aortic arch. This means that the distal portion would have less lumen volume and more polymeric material volume, thus reducing the likelihood that the distal end would kink and possibly block the flow of fluids through one of the channels **34, 36 or 38**. Thus, another aspect of the invention is the catheter, wherein the distal portion that transcends (and bends around) the aortic arch, has fewer channels than the rest of the catheter. In this case, the obturator would only extend to the distal end of the blood flow channel and not to the inflatable bladder. In this case, the obturator would be significantly less than the full length of the catheter.

The outside diameter of the multichannel catheter of this invention will be such that it can be inserted and moved through the femoral artery of the patient and located in the ascending aorta as discussed above. Generally, this will have an outside diameter (OD) of no more than about 30 French, preferably of about 18 to 24 French with about 20 to 22 French outside diameter fitting most patients. The French scale is a scale used for denoting the size of catheters or other tubular instruments, with each unit being roughly equivalent to 0.33

millimeters (mm) in diameter. For example, 18 French indicates a diameter of about 6 millimeters while 20 French would indicate a diameter of about 6.6 millimeters. The thickness of the wall **32** may be between about 0.2 mm to about 1.0 mm. Thus, the inside diameter of channel **34** will generally not exceed about 28.2 French, and may vary from about 14.8-22.5 French.

The obturator **146** of this invention as shown in Figure 12A, has a solid, flexible shaft **134** to slidably engage the blood-flow channel to block the flow of blood. The shaft **134** has a distal portion **130** for inserting into the channel and a proximal portion **148** that comprises a handle **138** for pushing the distal portion **130** into the lumen to be blocked or pulling the distal portion out of the lumen. Generally, the distal portion **148** has a cross-section that is less than the cross-section of the handle **138** and will have a cross-sectional dimension, which, at its widest part, is of a size that is no larger than the inside dimension of the blood delivery tube that is inserted into an artery such as a femoral artery, for delivery blood to a mammal particularly a human. Thus, the cross-sectional dimension will be no more than about 28.2 French (i.e. about 9.4mm) and may vary from about 14.8-22.5 French. It is preferably no more than about 21 French (about 7.0 mm), and more preferably less than about 18 French (about 6.0mm). The cross-sectional configuration will be one that conforms to the cross-sectional configuration of the lumen that the obturator shaft is blocking. It may have a circular, square, trapezoidal, or other design, but generally will be circular with adjustments made for the internal shape of the lumen. Examples can be seen in Figures 5A-5E, 6A-6B and 12B. Figure 12B is a cross-section of the obturator of Figure 12A along lines J – J. Here the cross-section is circular with portions **140** of the circle removed to accommodate certain channels in the lumen into which the shaft is inserted. This is better depicted in Figure 10B, which shows the shaft **134** of Figure 12A in place in a multi-lumen catheter.

In some cases, it may be useful to provide the multichannel catheter of this invention with a distal end that has a slight "preshaped" region designed into it. The preshaped region is designed to correlate to the aortic arch. In inserting the catheter the preshaped region is maintained in a relatively straight condition by using a stylet, i.e., a stiff plastic support mechanism positioned in channel **34**. This can be used in conjunction with a guide wire positioned in channel **36**. When the distal end of the catheter reaches the curve of the aortic arch, the catheter continues to be advanced via the femoral artery, but the stylet is slowly

withdrawn allowing the precurved region to bend around the aortic arch to have the balloon then located past the brachiocephalic artery but before the coronary ostia.

In other cases it may be useful not to have a preshaped distal region but instead have a straight end that is of a durometer rating that allows it to transcend the aortic arch by following the arch, making a "U" turn of essentially 180°, allowing the balloon to be properly positioned for inflation in a stable position. This may be achieved by bonding a distal portion that has only the two smaller lumens **36** and **38**, thus making the distal portion less susceptible to kinking, as discussed above.

As shown in the FIG. 10A, at the distal end **101** of the catheter of this invention there is located a inflatable bladder **42** which in general is a balloon that is attached to the distal end of the catheter. The interior of the inflatable bladder is in fluid communication with the third channel **38** so that the balloon can be inflated or deflated by transporting fluid through the channel to the balloon to inflate it, or sucking the fluid out to deflate the balloon. The design of the balloon may be any design known in the art, such as that shown in U.S. Patent number 5,423,745; 5,516,336; 5,487,730; and 5,411,479, the pertinent parts of which are incorporated by reference. Useful balloon components are commercially available to one of ordinary skill. While one balloon is shown in FIGS. 9, 10A and 16, multiple balloons could be used, e.g., two. However, for ease of use and preparation, one balloon is preferred. It is also preferred that the distance between the proximal edge **44** of the balloon and the distal side **45** as shown in Figure 16 be such that the surface contact of the wall of the balloon with the interior wall of the ascending aorta wall be maximized. This helps ensure a tight seal to prevent leakage. This distance between **44** and **45** may be from about 20 mm to about 50 mm, preferably about 30 mm to about 40 mm.

Turning now to Figure 10B, one sees a closeup of the distal end **102** of the catheter of the invention. It should be understood that the figures are representative, and are not necessarily drawn to scale. This is an external view that shows the elongate openings **40** and a balloon **42** in its inflated form, although not fully inflated. In general, the balloon is preferably of an oblong shape (i.e., its longitudinal cross-section appears to be cylindrical) as shown in Figures 8 and 16. This maximizes the surface contact with the ascending aorta wall and minimizes the stress on the vessel wall by dispersing the pressure over a greater area. By maximizing the surface contact, the position is maintained to a greater extent.

The forces imposed upon the wall of the ascending aorta are evenly distributed over the surface area contacted using a cylindrical balloon such as that disclosed in the multichannel aortic balloon catheter of the invention, and shown in Figure 15. A spherical balloon, such as Heartport's catheter model EARC-23EAC, known in the art, concentrates and directs all of the force towards a smaller area of aortic wall near the apex of it's curvature. While the magnitude of the concentrated force from a spherical balloon is equivalent to that of a cylindrical balloon, a distributed force resulting from a cylindrical balloon poses less problems in terms of balloon stability. This is due to the fact that the cylindrical balloons tend to naturally orient the forces perpendicular to the aortic wall more so than a balloon which is spherical in shape by distributing the force over a larger surface area.

Applicant's cylindrical balloon as shown in Figure 15 cannot "pivot" within the ascending aorta as easily as a spherical balloon due to the increased surface contact with the wall of the ascending aorta and has, therefore, an increased propensity for stability.

The design of the distal portion of the multichannel catheter of the invention that transcends the aortic arch is such that the radial forces exerted by the tip of the catheter are less influenced by curvature or angulation of the shaft of the catheter. That is, there is a change (reduction) of structural rigidity of the catheter from the end of the blood flow lumen 34 to the distal end of the device. This facilitates positioning of the catheter tip. The balloon located on or around the catheter can be used to position (or control position) the catheter in the desired orientation within the ascending aorta. This "desired" position can be a central or eccentric location. The shape, size, materials, mounting and physical characteristics of the balloon can be modified as so to control the desired positioning of the catheter within the blood vessel.

Forces that influence the balloon stability include those of the balloon against the aortic wall, those of the wall against the balloon, and those exerted by the catheter shaft (e.g. leverage and torsion). These forces will continue to search for a point of balance until it is found. Until balance is obtained the balloon will remain unstable within the ascending aorta.

Asymmetrically mounted balloons, such as Heartport's, known in the art, provide greater opportunity for instability due to their inability to effectively balance the opposing forces between the balloon and the wall of the ascending aorta.

Applicant's preferred balloon as shown in Figure 16 is designed to be symmetrically mounted, providing the best opportunity to balance and equalize the opposing forces between the balloon and the wall of the ascending aorta.

Balloon taper should be minimized in order to maintain cylindrical profiles as shown in Figure 15. Tapered balloons may orient the catheter tip towards the outside of the aortic arch. As the balloon is then inflated the inflation axis of the balloon (perpendicular to the catheter shaft) is not oriented perpendicular to the walls of the aortic arch, its orientation becomes increasingly parallel to the walls of the aortic arch. This then allows the balloon to continue it's expansion parallel to the aortic arch which in turn forces the catheter tip into the wall of the ascending aorta possibly resulting in occlusion of the cardioplegia lumen.

To prevent occlusion of the cardiplegia lumen and/or damage to the inside wall of the aorta, the physician or assistant can monitor the progress of the ascending multichannel catheter of the invention into the aorta. Transesopohageal Echocardiography (TEE) monitoring or Fluoroscopic Monitoring are useful to monitor balloon occlusion function.

While the surface of the balloon may be smooth, as shown in FIG. 15, it preferably has a design on it that provides additional friction between the balloon surface and the internal surface of the aortic arch. Thus the balloon surface may have either depressions **150**, as shown in FIG. 8, or ridges **152**, as shown in FIG. 13 in a design that helps maintain the balloon's position. It is preferable to have on the surface of the balloon certain ridges or bumps indicated in FIG. 13 as **152** to provide additional friction for maintaining the position of the balloon in place and minimizing the disruption of plaque that may be present. Generally, the volume of the balloon will be about 30 to about 100 cubic centimeters, preferably about 30-60 cc. The length of the balloon from its proximal end **44** to its distal end 45 will generally be about 2.5 cm to about 7.5 cm with about 4 cm being particularly satisfactory. It will need to expand sufficiently to block the ascending aorta completely so that blood does not get to the arrested heart from the cardiopulmonary machine.

Turning again to Figure 4, the second channel **36** is designed to introduce a cardioplegia solution, to evacuate fluid (i.e., vent the left ventricle), or to carry a guidewire or various types of probes for treating the heart. Thus, it has at least one opening **37** at the distal end **33** of catheter **100** downstream of balloon **42**. This allows a cardioplegia solution or the appropriate fiberoptic cable to be inserted into the channel and moved through the channel

out exit **37**. It also allows for a negative pressure to be applied to vent the left ventricle of the heart.

In a preferred mode of operation, the catheter of this invention is inserted percutaneously or by cutdown into the femoral artery of a patient and is threaded through the femoral artery to the ascending aorta to be positioned there. It may be necessary to supplement the flow of a patient's heart if it has been weakened, and this can be done by flowing oxygenated blood through the central passageway **34** out the outlets **40** to the great arteries and other arteries in the arterial system. If an operation is to be performed on the heart, which requires arrest of the heart, the catheter is positioned appropriately, the balloon is inflated to block the flow of blood into the heart from outflow openings **40**. Cardioplegia solution is administered through channel **36** out opening **37** to arrest the heart and blood is circulated through channel **34** out openings **40** to maintain circulation of oxygenated blood in the patient during the operation.

Turning now to FIGS. 5A through 5E and FIG. 6A - 6B, one can see a cross-sectional view taken along lines 5--5 in FIG. 4. In these figures, it can be seen that the large central passageway **34** is defined by the wall **32** of the overall catheter and that the channels **36** and **38** are integrated into the wall **32**. They may be integrated so that they are positioned more interiorly as shown in FIG. 5A or more exteriorly as shown in FIG. 5B with cross-sectional diameters that are essentially a circle. On the other hand, in FIG. 5C, the cross-sectional of channels **36** and **38** may be elongated, oval, or of a "bow-tie" configuration. Other examples of possible configurations of channels **36** and **38** are shown in Figures 5D and 5E. While the relative volumes of the two are shown to be about equal, the total volume of flow available for all passageways **34, 36** and **38** is divided as follows. The amount of fluid flowing through passageway **34** will be at least about fifty percent or more (e.g., up to about 90%) in order to achieve the advantages of this invention with the flow through passageways **36** and **38** being the remaining fifty percent or less (i.e., down to about 10%). In general, there will need to be less volume in the channel for communicating with the balloon than in the channel that is available for the cardioplegia or the fiberoptic instruments or cable. While generally, it is preferable to have the channels **36** and **38** opposed one hundred eighty degrees from each other as shown, for example, in FIGS. 5A to 5C and 6B, it may be possible to have them adjacent as shown in FIG. 5E. Having them adjacent makes the preparation a bit more difficult than having them opposed as in FIGS. 6A-6B.

The ratio of the total volume of the cardioplegia channel **36** to the balloon inflating channel **38** will vary from about 1:1 to about 4:1. So, for a multichannel catheter in which about 70% of the total available volume is provided for the channel **34** and about 30% of the total available volume is provided for channels **36** and **38**, channel **36** will account for about 15% to about 24% with channel **38** accounting for about 15% to about 6%. Alternatively if channels **36** and **38** collectively account for about 10% of the total available volume then channel **36** will have about 5% to about 8% while channel **38** will have about 5% to about 2%.

By referring to FIG. 7, one can see the relative proportions of the three channels of the multi-channel catheter of this invention. In the Figure the abbreviations have the following meanings:

ID--inner diameter

OD--outside diameter

IWT--inner wall thickness

OWT--outer wall thickness

Summarizing the dimensions, they are as follows:

OD 32: 16-30 French (5.3-9.9 mm)

ID 32: 14.8-28.2 French (4.7-9.3 mm)

OWT 32: 0.6-1.0 French (0.2-0.3 mm)

IWT 41: 0.6-1.0 French (0.2-0.3 mm)

ID 38: 0.6-1.0 French (0.2-0.3 mm)

ID 36: 0.6-4.0 French (0.2-1.3 mm)

The catheter of this invention is able to handle a blood flow rate through the central channel **34** of about one-half up to about 6 liters per minute with the proper sizing and design. Generally, a flow of about five liters per minute is sufficient to handle the vast majority of circulatory needs required by patients having heart surgery performed. On the other hand, the flow of cardioplegia solution or drug-containing solution through channel **36** is generally about 100 to about 300 cubic centimeters (0.1-0.3 liters) per minute. The balloon inflation channel **38**, which is generally smaller than channel **36**, will be of a size sufficient to carry balloon-inflating fluid, e.g., saline, to the balloon. The volume of the balloon is generally

about 40 cc to about 100 cc, generally about 60 cc. Thus, channel 38 is of a size sufficient to carry that volume over a short period of time, i.e., less than a minute and generally less than about 10 seconds. The volume of the balloon will be greater if the distal end of the multichannel catheter is tapered in the region covered by the balloon.

In general, the catheter of this invention will need to be flexible enough to easily be inserted up through the femoral artery to be positioned in the ascending aorta. The flexibility needs to be sufficient so that the catheter can bend but will not kink at body temperature. In general, this flexibility is measured by Durometer and will be in the 50 to 80 range. Generally, we will have a Durometer reading of about 60. It is preferable that the distal end where the balloon is located is somewhat stiffer than the rest of the catheter. This helps to ensure the positioning of the balloon in the ascending aorta to ensure that it does not get displaced during the operation.

In performing open heart or less invasive cardiac surgery, generally, it is necessary to do an angiogram by placing an angiogram catheter up the femoral artery and positioning it in the ascending aorta. Based on the length of the angiogram catheter, balloon placement position can be determined, the multi-channel catheter of this invention has markings indicating its length measured from the distal end to various distances near the proximal end so that the physician knows exactly how far to insert the catheter of this invention. Having that information indicated on the catheter makes it easier for the physician to do the insertion and also reduces the need to use fluoroscopy to properly insert the catheter. On the other hand, if a angiogram catheter measurement is not done before inserting the catheter of this invention, an ultrasound probe may be used to position the catheter of this invention where the catheter of this invention carries a detectable beam on the tip of the catheter. Alternative methods may be employed for positioning the catheter, such as guidance by fluoroscopy or echocardiography, fiberoptic visualization through the catheter, magnetic or electronic guidance, or other means of insuring proper placement.

The material which is used to manufacture the multichannel catheter of this invention may be any material that is physiologically acceptable, that is it is made of a material that will not have an adverse effect on the patient when used in the manner in which it is intended. Generally this will require the use of biocompatible material (i.e. the body will not react with it) for preparing the catheter of this invention. In addition, the material that is used must possess sufficient stability and flexibility to permit its use in accordance with the process of the invention. Various biocompatible polymers may be used. A polymer that is particularly

valuable for preparing the catheter of this invention is polyvinyl chloride (PVC) blood tubing, that has been plasticized. Preferably, the plasticizer which is used in the PVC is trioctyl trimellitate (TOTM), while the standard plasticizer is di-(2-ethyl-hexyl) phthalate (DEHP). TOTM plasticizer is less extractable than DEHP and produces a better blood response. Suitable PVC resin is available from Dow Chemical Corp., Midland, Mich., or Polymer Technology Group (P.T.G.) Inc., Emeryville, Calif. Another polymer that is useful for preparing the multichannel catheter of this invention is medical grade polyurethane. Other polymers may be prepared based on a family of polysiloxane-containing copolymers termed surface modified additions (SMAs). These copolymers may be blended with the base polymer before processing or coated on the blood contacting surface. When blended with the base polymer the SMA will migrate to the polymer surface resulting in a high concentration of the SMA of that surface, which has fewer adverse reactions with the blood that contacts it. When coated, device surfaces are pure SMA. High surface concentrations of the SMA are responsible for the improved biocompatibility of extracorporeal circuit components. Plasticized PVC is particularly useful as the base polymer. A further description of these polymers is given in article entitled "Surface Modifying Additives for Improved Device-Blood Compatibility" from ASAR Journal 1994 M619-M624 by Chi-Chun Tsai et al. The article is incorporated herein by reference. Such polymers are available from P.T.G. Corp.

Other useful polymers include polyurethane-urea biomaterials that are segmented polyurethane (SPU) some of which have surface-modifying end groups (SMES) covalently bonded to the base polymer. These are described by Ward, et al. in an article entitled "Development of a New Family of Polyurethaneurea Biomaterials" in Proceedings From the Eighth Cimtec--Forum on New Materials Topical Symposium VIII, Materials in Clinical Applications, Florence, Italy, July, 1994. See also U.S. Patent application Ser. No. 08/221,666, which is incorporated herein by reference.

Sometime the blood interacts with artificial surfaces of polymers in such a way that the blood coagulates on the surface creating thrombi. These thrombi can block the catheter or blood vessels, preventing the blood from flowing and causing oxygen depletion and nutrient starvation of the tissues. Thus, the surface of the polymeric material used for the multichannel catheter of this invention should not give rise to thrombus formation. An anti-thrombotic agent can be used to prevent the clots from forming. Some of the blood polymer interactions are discussed in article entitled "Biomaterials in Cardiopulmonary Bypass" found in Perfusion 1994; 9: 3-10 by James M. Courtney et al.

Polymer modifications that permit an improvement in blood compatibility while maintaining acceptable levels of other fundamental properties include the treatment of surfaces with protein, the attachment of anti-thrombotic agents and the preparation of biomembrane-mimetic surfaces. The preferred anti-thrombotic agent is the anti-coagulant heparin which can be attached ionically or covalently. Preferably it is attached covalently.

An additional factor to consider in preparing the catheter of this invention is the relative roughness of the blood-contacting surface. Excess surface roughness has deleterious effects on blood flow through the catheter and should be avoided.

Another article that discusses the factors relating to compatibility of surfaces contacting blood is entitled "State-of-the-Art Approaches for Blood Compatibility" from Proceedings of the American Academy of Cardiovascular Perfusion Vol. 13, January 1992, pages 130-132 by Marc E. Voorhees, et al.

Turning now to Figures 9, 10A, 10B and 11 one can see an overall view of the catheter of this invention. The catheter is generally shown as **100** having a distal end **101** and a proximal end **102**. At the distal end one sees the inflatable bladder, or balloon, **42**. Along the length of the catheter are a series of ports or openings **40**, which allow blood to flow through the large inner channel, as discussed hereinbefore. The obturator or flexible shaft is shown in part as **146**, with an enlarged handle portion **138** and a reduced distal portion **148** that slidingly engages the internal channel, not shown, to block the backflow of blood once the catheter is inserted into a femoral artery. The obturator **146** (in Figure 12A) is shown in Figure 9 as being partially withdrawn from the internal channel. An enlargement of the obturator end inserted into the internal channel is shown in Figure 10A as encompassed in the area defined by a dotted line. The openings **40** are darkened to indicate that the obturator is positioned to block all of the outlet ports. Once the obturator is inserted into a patient's femoral artery the tip of the obturator is drawn through the blood flow channel until it is located proximal of the inlet port **108** for blood from a cardiopulmonary machine. The cardiopulmonary machine is connected so that the oxygenated blood enters the port **108** and then flows through the inner channel through the catheter and out through the ports **40** to then circulate to the arteries of the patient. At the distal end of the catheter, the channel for, *i.a.*, the cardioplegia solution is attached to a cardioplegia line **114** which in turn leads to a port **115** for the import of cardioplegia fluid which can be pumped through line **114** and the inner channel out through the cardioplegia outlet port **119** at the distal end of the catheter. A port **116** is available for monitoring the cardioplegia/aortic root pressure to determine if any

adjustments need to be made to the flow of the cardioplegia. A label **117** can be placed on the line **114** to ensure that the doctor knows which line is for the cardioplegia. A hemostatic valve **122** is shown through which a guide wire can be threaded as discussed hereinafter. At the proximal end **102** of the catheter **100** there is a connection for a line **109** for the balloon inflation fluid to enter the channel that leads through the interior of the catheter to the balloon at the distal end **101** of the catheter **100**. Attached to the balloon inflation fluid line is a port **110** for connecting to the syringe containing the balloon inflation fluid. Also located at the proximal end of the catheter is a port **111** for monitoring the balloon inflation pressure to insure that enough pressure is provided to the balloon. A label **112** will label the line for the balloon inflation fluid. The distal end of the obturator is shown at **160** by means of a solid line, even though the obturator is inside the catheter. In Figure 9 the obturator is partially withdrawn. As the obturator is withdrawn further and further eventually the end of the obturator will be drawn to a point where it is proximal to, *i.e.* to the left of, the inlet port **108** for the blood. The oxygenated blood from the cardiopulmonary machine will then enter the port **108** and flow through the inner blood flow channel and out through the ports **40**. The flow of the blood can be adjusted by clamping the flexible connecting hose **113** with a suitable pinch clamp. This can affect the flow of blood through the catheter.

Figures 10A and 10B show a similar view of the catheter of this invention. The necessary attachments for the cardioplegia, blood flow, and the balloon inflation fluid. The numerals in 10A and 10B are similar to those used in Figure 9. In Figure 11, a close-up of a portion of the proximal end **102** of the catheter is shown where the positioning indicators **121** are marked. At the right hand side of the Figure 11, a warning indicator **120** is located which would be for example, 25 mm from the first outlet port **40** shown in the figure. This is useful as one is withdrawing the catheter from a patient as a warning that an outlet port would be appearing soon and that the obturator should therefore be positioned back in the blood flow channel to prevent the backflow of blood once the heart has resumed its beating and pumping of blood. The other positioning indicators **121** shown as V, VI and VII show the number of centimeters, *e.g.* fifty, sixty, or seventy respectively, from the distal tip VII of the catheter. These are useful to help the surgeon position the catheter prior to surgery when the exact distance to the ascending aorta has been determined. The serial number SN000000 is shown to identify the device that is being used.

Turning now to Figure 13, one sees the catheter of this invention positioned with the balloon **42** located and expanded in the ascending aorta. The catheter is shown as being

shaded in the proximal portion 102 to represent the obturator (being inserted) into the catheter to the point where the distal portion transcends the aortic arch. Thus the portion transcending the aortic arch has only 2 channels: one that leads to outlet 199 and one that leads to the interior of the balloon **42**. The handle 106 of obturator can be used to withdraw the obturator from the blood flow channel to a point where the obturator is no longer blocking port **108.** A cardiopulmonary machine can be attached to port **108** to allow oxygenated blood to flow into the catheter and our the blood flow ports **40**, not shown in the drawing.

Turning now to Figures 14A, 14B, and 14C, one can see a cross-sectional view of the distal portion of the catheter of Figure 13. Figure 14A and 14C depict two-channel arrangements, while 14B depicts a three channel arrangement. In these figures, the numerals have the same designation as those in Figures 5A-5E. Thus 36 designates the cardioplegia or venting channel and 38 designates the balloon-fluid channel. The shaded portion represents polymeric material.

Uses of the Catheter of This Invention

The catheter of this invention may be used in several different ways. For a condition in a patient that needs supplementary extracorporeal blood circulation because of insufficient circulation from his or her own heart, the catheter may be introduced via a femoral artery, positioned as appropriate and attached to a cardiopulmonary bypass machine to circulate blood through the large central channel **34** and out openings **40**. When appropriately positioned with the distal end of the catheter in the ascending aorta, a fine fiber optic cable may be threaded through second channel **36** to examine the aortic area of the heart. If it is determined that a heart operation is necessary, the balloon may be inflated through channel **38** to block the ascending aorta, cardioplegia solution may be administered through channel **36** to arrest the heart, and oxygenated blood from a cardiopulmonary machine is pumped through channel **34** and openings **40** into the arterial pathway of the patient's circulatory system. Thus, the device of this invention may be used in cardiovascular surgery in general or various heart examinations or treatments of artery and valvular disease. Cardiovascular surgery is meant to include surgery to the heart or to the vascular system of a patient. The catheter is particularly useful in cardiac surgery, whether open chest surgery or minimally invasive heart surgery. Such surgery may include, but are not limited to, the following:

1. Coronary artery revascularization such as:

(a) transluminated balloon angioplasty, intracoronary stenting or treatment with atherectomy by mechanical means or laser into the coronary arteries via one lumen of the catheter or

(b) surgical mobilization of one or both of the mammary arteries with revascularization achieved by distal anastomoses of the internal mammary arteries to coronary arteries via a small thoracotomy.

2. Any atrial or ventricular septal defect repair such as by

(a) "closed" cardioscopic closure or

(b) closure as in "open" procedure via a thoracotomy or other limited access incision.

3. Sinus venosus defect repair similar to above.

4. Infundibular stenosis relief by cardioscopic techniques.

5. Pulmonary valvular stenosis relief by cardioscopic techniques.

6. Mitral valve surgery via thoracotomy.

7. Aortic stenosis relief by the introduction of instrumentation via a lumen in the aortic catheter into the aortic root.

8. Left ventricular aneurysm repair via a small left anterior thoracotomy.

One unique aspect of the multichannel catheter of this invention is its ability to be adapted to be used in accordance with the needs of a patient. For example, a patient with symptomatic coronary artery disease undergoes a diagnostic evaluation to determine the type of treatment that best suits that patient's condition. As a result of the evaluation, the physician may recommend surgical treatment, interventional cardiology treatment or some alternative treatment. Interventional treatment may include percutaneous transluminal coronary angioplasty, atherectomy or the use of a stent to keep the vessels open. Alternative treatment may include the use of a laser or myoplasty.

If additional treatment is recommended, the multichannel catheter of this invention is particularly valuable in the further evaluation to determine the condition of the patient, the type of treatment recommended and the type of drugs that might be useful to administer to the patient. Thus, in using the multichannel catheter of this invention, the catheter is inserted

into a femoral artery by percutaneous puncture or direct cut-dow. The distal end of the catheter, which carries the balloon, is inserted first and moved through the femoral artery to be positioned in the ascending aorta, as discussed in more detail hereinafter. Initially, the physician performing the work may wish to introduce instruments through the channel **36** in FIG. 4 or other probes to allow observation or measurement of the internal condition of the artery, aortic arch and/or aortic semilunar valve. A cardioscope, an electrophysiology probe, a transmyocardial revascularization probe, a radiation probe, or the like may also be inserted through channel **36**. Once observations are made concerning the condition of the heart and associated arteries, the physician can then take additional steps. For example, it may be desirable to administer a biologically active fluid directly to the heart or aorta using an appropriate liquid composition containing an active entity appropriate for the patient's condition. The active entities in such a biologically active fluid include drugs (particularly those having cardiovascular effect) that are pharmaceutically acceptable small organic molecules, small polypeptide molecules, larger polypeptide molecules, and even a DNA or RNA that may be useful for gene therapy. Examples of useful molecules include those useful as antianginals (e.g., organic nitrates, calcium channel blockers, beta-adrenergic antagonists) antihypertensive, antiarrhythmics, antihyperlipoproteinemias, myocardial contractile enhancers, anti-atherosclerotic agents, and the like. Such fluids especially for cardioplegia can best be delivered through channel **36** in FIG. 4, but alternatively can be delivered in the fluid used to inflate balloon **42** through channel **38** in FIG. 4. In the latter case, the material used for the balloon would be semipermeable to allow the drug to diffuse through the balloon membrane. A drug having lipid-dissolving characteristics can be delivered through the balloon membrane. Alternatively, it may be useful to deliver such an active agent by adding it to the cardiopulmonary machine reservoir.

Once the catheter is in place, and observations regarding the internal conditions have been made, the physician and/or assistant can then move on to the next steps. For example, less invasive surgery, as discussed in U.S. Patent number 5,452,733, may be performed on a beating heart with no initial cardiopulmonary support, i.e., no blood would flow through the catheter and heart would continue to function. If at any time, the physician would decide that cardiopulmonary support would be needed, supplemental blood flow from a cardiopulmonary (heart/lung) machine could be started and work could be continued with a beating heart or a fibrillating heart. Once a decision is made to completely arrest the heart, cardioplegia solution is delivered to the heart through the channel **36** after balloon **42** is inflated to block

the flow of blood to the heart from the cardiopulmonary machine. As described, the multichannel catheter of the invention can be used in least invasive surgical procedures as well as open chest surgery.

The multichannel catheter of this invention is particularly useful in performing heart surgery where the heart is arrested using a cardioplegic solution and blood is circulated to the patient via a cardiopulmonary bypass machine. In this case oxygenated blood is circulated through the large channel of the catheter of this invention. The introduction of negative pressure on the venous drainage system may be used to enhance venous drainage and reduce the need to vent the right side of the heart. Generally, the negative pressure may be maintained at the vena cavae regions (superior and inferior) using a centrifugal pump attached to a standard femoral venous cannula. A system for performing such a process is depicted in FIG. 8.

In general, the process for preparing for cardiovascular surgery or for performing surgery on a patient's heart comprises a sequence of steps, which from the standpoint of using the catheter of this invention, includes three steps that are performed sequentially: (a) once a cut-down or percutaneous opening is made in the patient to access *e.g.* the femoral artery, the distal end of the catheter described herein is inserted into the femoral artery (the flexible shaft or obturator is slidingly engaged in the blood flow channel to prevent backflow of blood); (b) the catheter is positioned so that the inflatable balloon is positioned in the ascending aorta; and (c) the obturator is removed, *i.e.* withdrawn sufficiently, to allow the blood flow channel to be connected to a cardiopulmonary machine to pump blood into the channel at its proximal end. Prior to, during, or after insertion of the catheter into the femoral artery, a single femoral access cannula is inserted into the patient's femoral vein to position it so the distal open end of the cannula is adjacent the vena cava region of the patient's heart and the proximal end of the cannula is attached to a cardiopulmonary bypass machine through a centrifugal pump wherein the cardiopulmonary bypass machine comprises a blood oxygenation means fluidly connected to the centrifugal pump.

The multichannel catheter is positioned within the subject's blood circulatory system such that the distal end of said catheter is positioned in the ascending aorta such that the first channel openings are located along the distal length of the catheter (as discussed before), the inflatable means is located on the cephalid side of the aortic valve and the distal end of the second channel is located proximate the aortic valve and downstream of the inflatable means.

About the time a source of oxygenated blood from the cardiopulmonary machine is connected to the proximal end of said first channel of the catheter, a source of cardioplegia fluid is connected to the proximal end of said second channel. A source of fluid is connected for inflating the balloon to the proximal end of said third channel and the balloon is inflated to block the flow of blood to the heart.

Cardioplegia solution is pumped into the heart to arrest the patient's heart. With the obturator withdrawn, oxygen-rich blood is pumped through said first channel out the first channel openings upstream of the balloon at rate sufficient to maintain the subject's metabolism and perfusion while at the same time oxygen-depleted blood is removed from the patient's vena cavae regions through the femoral vein cannula by applying a negative pressure using the centrifugal pump. The physician can then perform a surgical operation on the heart as needed and the patient is maintained as needed.

Referring to FIG. 8, the femoral vein is accessed percutaneously or by cut down using the appropriate size standard femoral access cannula **50** (such as an Research Medical Inc. #TF-030-050). This cannula conducts de-oxygenated venous blood from the vena cava **51** to PVC tubing **52** (e.g. 0.5 inch inner diameter). This tubing is attached to the negative pressure (inlet) port **53** of a centrifugal pumping device **54** (such as the St. Jude Medical #2100CP); the positive pressure (outlet) port **55** of the centrifugal pumping device is connected via tubing **56** (0.5 inch ID PVC) to a venous reservoir system **57** (such as the COBE Cardiovascular, Inc. VRB 1800). This configuration pulls blood from the vena cava **51** to the venous reservoir **57**. Utilization of negative pressure in this manner to provide venous blood return eliminates the need to "vent" or empty the right heart. By using a centrifugal pump that reaches about -20 to about -50 millimeters of mercury (mm Hg), a sufficient negative pressure is maintained. The use of a closed reservoir system is preferred to eliminate air/blood interface and associated blood trauma. The venous blood exits the reservoir through tube **58** (e.g. 3/8 inch ID PVC tubing). This tube is connected to an oxygenator/heat exchanger means **59** (such as the COBE Cardiovascular, Inc. model #CML DUO #050-257-000) to oxygenate the oxygen-depleted blood. The blood will be pumped through the membrane/heat exchanger by a roller pump device **60** (such as the COBE Cardiovascular, Inc. model #043-600-000). The oxygenator will oxygenate the blood and the heat exchanger will regulate blood temperature. The oxygenated arterial blood will exit means **59** through tube **61** (such as 3/8 inch ID tubing), pass through an arterial filter **62** (such as a COBE Cardiovascular, Inc. Sentry #020-954-000) and be delivered into the femoral

artery via the multichannel catheter **100** of this invention. Preferably, all blood contact components are surface modified to reduce blood trauma and patient inflammatory response and to meet requirements for anticoagulation of patient's blood.

The multichannel cathether **100** of this invention provides a flow of oxygenated blood to the aorta **64**. The invention catheter **100** is introduced into the femoral artery **65** percutaneously or by cut-down. The invention catheter **100** may be introduced utilizing a guidewire and stylet. The stylet provides stability to the catheter allowing the device to resist kinking during insertion with a minimum required wall thickness of the catheter. Accurate positioning of the balloon will differ from other positioning methods by utilizing measurement of the catheter. The appropriate distance will be determined and indicated on the femoral artery catheter **100** prior to insertion; the positioning indicators **121** and warning indicator **120** will provide simple and accurate balloon positioning. Accurate positioning of the balloon tip may also be enhanced or verified using visualization by transesophogial echo or fluoroscopy.

The invention catheter provides a flow of oxygenated blood to the aorta as part of the cardiopulmonary bypass process. The catheter is of a length sufficient to extend from the insertion point in the femoral artery to the ascending aorta as shown in FIG. 8, which length will vary depending on the size of the patient, as discussed hereinbefore. The catheter has a proximal end **102** and a distal end **101**. The catheter has an inflatable balloon **42** located on the proximal side of the distal tip for fixing the catheter within the ascending aorta. The channel extending the length of the catheter to the balloon has a port at the proximal end of the catheter that communicates with the balloon so that the balloon can be filled with a fluid from a syringe-type inflation device **73** to occlude the ascending aorta as discussed herein. The catheter also has (a) a channel extending from the proximal end **102** to outlet ports **40** upstream of the balloon for delivering oxygenated blood and (b) a channel extending through the entire cannula with an outlet port **78** in the distal tip for a guidewire and/or delivering a cardioplegia solution to the heart through stopcock **68** into inlet line **109** at the end of line **69**. Changing the position of the valve in stopcock **68** to connect with line **70** and providing a negative pressure by roller pump **72**, allows for the venting of the left ventricle by pulling fluid from the left ventricle through the semilunar valve through opening **78**. Optionally, a line is available for optical fibers to be inserted at port 71.

Another aspect of this invention may be viewed as an improvement in the process of minimally or "least" invasive heart surgery. For traditional open heart surgery, the surgeon is

required to make a long incision in the front of the chest and divide the sternum bone to gain access for the procedure. In minimally invasive heart surgery, a series 4-7 of small incisions are made and the operation is carried out through narrow tubes or ports, using direct or video assisted visualization. Such a minimally invasive process and associated techniques are described in various aspects in U.S. Patent number 5,433,700; 5,458,574; and 5,452,733, all of which are incorporated by reference in their entirety.

How to Make the Catheter

Generally the multichannel catheter of this invention is prepared using any technique that provides the multichannel catheter herein described. The key is to ensure that the second and third channels are integrated into the wall of the first channel. This may be done by forming the channels separately then conjoining them, i.e. by gluing or other means. However, the multichannel catheter may be made through a mandrel-dipping technique, or preferably a continuous extrusion process. Extrusion involves forcing a fluid polymer material (as discussed above) through a suitably-shaped die to produce the cross-sectional shape, such as that depicted in FIGS. 5A through 5E and 6, or other suitable shape as described herein. The extruding force may be exerted by any standard means known in the art such as by a piston or ram or by a rotating screw, which operates within a cylinder in which the polymeric material such as PVC or polyurethane is heated and fluidized. The fluid material is then extruded through the die in a continuous flow. The extrusion head will have a multitubular die to provide a continuous multichannel catheter, essentially as described herein. Using a mandrel-dipping technique, a mandrel having the desired size and cross section design is dipped in or drawn through a fluid polymeric material so that the mandrel is coated with the polymer. The polymer is then dried on the mandrel and removed to give the desired design. This technique may be done at commercial manufacturers, e.g., PTG, Emeryville, Calif. or Extrusioneering, Temucula, California, and others.

Once the multichannel catheter is formed, whether by extrusion or mandrel-dipping, it is cut to suitable lengths and treated to provide the further characteristics of the product to make it operable. Such treatment may occur in any particular order. For example, a plurality of openings **40** in FIG. 4 are formed near the distal end of said catheter communicating with said first channel. These openings are made in conformance with the designs discussed herein, and thus are preferably elongate in that the longitudinal axis of the elongate design

may be helical or orthogonal, but is preferably substantially parallel to the longitudinal axis of the catheter itself. The openings may be provided by suitably cutting or punching the elongate design into the wall of the catheter. The design is approximately oval, rectangular, or the like with the length of the opening being about a size discussed herein before. The width of the opening will be such it will not weaken the structural integrity of the distal end of the catheter. FIGS. 8, 9 and 10 present various configurations for the positioning of openings 40. Optionally, additional openings communicating with the first channel may be provided along the length of the catheter positioned between approximately the middle of the catheter and the elongate openings near the distal end. The openings are useful in reducing the pressure drop between the proximal end of the catheter and the distal openings to help reduce the sheer stress on the blood.

In addition to the openings that communicate with the first, large channel, at least one opening communicates with the third channel. An inflatable bladder, i.e. a balloon device, is integrated into the distal end of the catheter such that the interior of the balloon communicates with the outlet of the third channel to allow fluid to flow through the third channel and to the interior of the inflatable means. In general, this may be integrated by positioning a balloon having an opening corresponding to the opening to the third channel and adhering the balloon to the distal end of the catheter between the openings to the first large channel of the catheter and the distal tip of the catheter. This adherence may be performed by using a suitable glue, solvent bond, light sensitive weld, or other suitable material known in the art for this purpose. The material used for the inflatable means may be any suitable biocompatible material that is capable of being inflated and deflated a plurality of times. Polyurethane-based biocompatible polymers are preferred. These are described in the aforementioned article by Ward, et al.

Finally, the distal end of the first, large channel and the third, small channel are closed. This may be achieved by plugging, solvent sealing, heating or other suitable means. The process must be carried out in such a way that the distal end of the second channel remains open.

Alternatively, a catheter of this invention may be constructed by conjoining, e.g. a 3 or 4 channel portion (which has the large blood flood channel) with a portion that has one less channel, i.e. the distal portion in Figure 13.

In this case, the catheter is produced by introducing, e.g. 3 or 4 single lumen extruded tubings into a molded manifold which merges each of the single lumens (3) into the mulitlumen extrusion. See Figure(s) 5A-5D. The multilumen extrusion of the proximal portion is fused or bonded to the distal multilumens extrusion using mandrels which prevent closure of the continuing lumens, *e.g.* 36, 36a, 38 in Figures 5A-5D. The balloon is fused or bonded onto the distal portion of the tubing with fewer lumens, which portion is designed to transcend the aortic arch.

The proximal portion of the multichannel catheter of this invention is prepared using any technique that provides the multichannel catheter herein described. Once the proximal portion of the multichannel catheter is formed, whether by extrusion or mandrel-dipping, it is cut to suitable lengths and treated to provide the further characteristics of the product to make it operable.

The distal portion of the catheter is similarly extruded to give a length having a cross-section show in Figures 14A, 14B, or 14C. The openings of the distal portion (e.g. **36** and **38** of 14A) that correspond to openings of the proximal portion (e.g. **36** and **38** of Figure 5A) are aligned, mandrels are positioned to prevent a closure of the communicating lumens, and the distal and proximal portions are fused or bonded or otherwise permanently conjoined.

The inflatable bladder is integrated into the distal end of the catheter such that the interior of the balloon communicates with the outlet of the balloon communicating channel to allow fluid to flow through the lumen channel and to the interior of the inflatable means. In general, this may be integrated by positioning a balloon having an opening corresponding to the opening to the appropriate channel and adhering the balloon to the distal end of the catheter. As noted before this adherence may be performed by using a suitable glue, solvent bond, light sensitive weld, or other suitable means known in the art for this purpose. The material used for the inflatable means may be any suitable biocompatible material that is capable of being inflated and deflated a plurality of times. Polyurethane-based biocompatible polymers are preferred. These are described in the aforementioned article by Ward, et al.

Preparing A Patient for Cardiovascular Surgery Using A Catheter of the Invention

This is a representative process for using the catheter of this invention, given as a step-wise approach.

1. Preoperative screening of patients includes evaluation by sufficient methods (such as clinical examination, segmental doppler examination, aortogram) to exclude those with aortoiliac disease or anatomy that would preclude safe introduction of the catheter of this invention into the aorta from a femoral artery.

2. The patient is anesthetized, positioned, prepped and draped for cardiovascular surgery requiring, *e.g.* cardiopulmonary bypass. Arterial pressure is monitored using a right and left brachial or radial artery pressure monitoring line, which should be continuously simultaneously monitored, sudden differences in right and left pressure may indicate balloon blockage of innominate artery. Intraoperative monitoring with transesophageal echocardiography (TEE) is required. Fluoroscopy with capability of imaging the thoracic aorta may be used but is not an alternative to intraoperative monitoring with (TEE). The aortic arch and ascending aorta should be evaluated for the presence of atherosclerotic disease associated with luminal projections, a contraindication for use of the catheter of this invention. The aortic valve should be inspected for significant insufficiency, a contraindication for delivery of cardioplegia in the aortic root with the catheter of this invention.

3. The catheter of the invention is removed from its package using sterile techniques. The integrity of the occlusion balloon is checked by placing the distal end (balloon-tip) of the catheter into a basin of sterile saline solution while inflating the balloon with 20 cubin centimeters (cc) of air. If air bubbles are visualized leaking from balloon or balloon bond area the catheter is to be replaced. Air should then be removed by gentle aspiration, completely collapsing the balloon against the main body of the catheter. A 20cc syringe filled with normal saline solution should be used to prime the balloon and it's inflation channel. All air should be removed from the balloon and inflation channel by aspiration of fluid from balloon and channel. After priming and removal of air the stopcock valve to the balloon inflation channel should be closed leaving the balloon collapsed around the main body of the cathether (see Figures 9, 10A and 10B for diagram of port, lumen and component locations). To avoid potential over-inflation, less than 35 cubic centimeters (cc) of solution

should be reserved in the inflation syringe(s) for balloon inflation. The catheter of this invention (with the obturator) inserted is placed to the side for later insertion.

If Fluoroscopic visualization of the catheter and balloon inflation is desired, a dilute intravenous contrast solution (10% CONRAY® or equivalent), diluted to a total of approximately 2% contrast, should be prepared and used to prime the balloon and its inflation channel.

4. The common femoral artery on the side selected for introduction of the cannula is surgically exposed, obtaining proximal and distal control of the vessel and any significant branches.

5. The patient is systemically anticoagulated as appropriate for cardiopulmonary bypass using heparin administered intravenously, with activated clotting times (ACT) determined in the routine fashion. The catheter of the invention with hollow-needle obturator is inserted into the femoral artery, with free blood return verifying intralumenal tip location. The needle obturator is removed, and a .035 x 180 cm stiff guide wire is introduced through the cannula and advanced cephalad up the aorta and across the aortic arch to position the tip in the ascending aorta. TEE imaging should be used to verify proper guide wire placement in the ascending aorta. Fluoroscopic visualization of the guide wire placement may also be used if desired.

6. During brief occlusion of the femoral artery the short femoral cannula is removed and a 1 cm transverse arteriotomy is created encompassing the site of the wire entry across the anterior arterial wall. The .035 x 180cm Guide wire is back fed into the aortic root (for cardioplegia) of the catheter and through the hemostatic valve that comes attached to the lumen (see Figures 9, 10A and 10B for diagram of port, lumen and component locations). The valve is adjusted by tightening the thumbscrew of the hemostatic valve. The valve is tightened as much as possible while still allowing the guide wire to move freely through the valve. The guide wire is left in position until the catheter insertion is completed. Use of a soft-jaw clamp to control blood loss at femoral artery insertion site is recommended.

7. The catheter is advanced over the guide wire into the femoral artery through the short sheath. The catheter (with obturator) is advanced in a retrograde fashion up the lilac artery, abdominal aorta and thoracic aorta. The catheter is guided over the aortic arch with imaging assistance and the tip of the catheter is advanced into the ascending aorta. The position of the tip should be evaluated using TEE to verify that the tip is above and not interfering with the

aortic valve. If fluoroscopic visualization is desired, the radiopaque marker at the tip of the catheter can be used to assist placement. This will position the occlusion balloon in the ascending aorta, proximal to the origin of the innominate artery. In open sternotomy applications, tip position may be verified by direct palpation of the aortic root. The obturator is removed from the catheter, which is de-aired by allowing back bleeding, and then clamped at the 3/8 tubing area provided for clamping (see 113 of Figures 9, 10A and 10B for diagram of port, lumen and component locations). The obturator should be appropriately set aside for reinsertion, if required.

8. The blood flow lumen of the catheter is attached at port **108** (see Figure 9, 10A and 10B) to the arterial blood supply line from the CPB machine, taking care not to introduce air at the site of connection.

9. The inflation syringe filled with saline solution is attached via three-way valved manifold (stopcock) to the occlusion balloon control lumen. A pressure line from a suitable pressure monitoring device should be attached to the remaining valve port to monitor balloon inflation pressure (see Figures 9, 10A and 10B for diagram of port, lumen and component locations).

10. The aortic root lumen is attached via three-way valved manifold (stopcock) to the cardioplegia solution delivery/vent line from the CPB machine. Pressure line from suitable pressure monitoring device should be attached to remaining valve port **111** to monitor cardioplegia or aortic root pressure. The cardiopulmonary bypass machine vent line must be equipped with a ventricular vent valve to prevent excessive negative pressure on the vent line (see Figures 9, 10A and 10B for diagram of port, lumen and component locations).

11. Cardioplegic solution line pressure, aortic root pressure, and balloon inflation pressure are measured at the appropriate ports as indicated (see Figures 9, 10A, 10B for diagram of port, lumen and component locations)..

12. Venous cannulation is performed by direct cannulation of the right atrium with a single or dual-stage cannula, selected cannulation of the superior and inferior vena cavas, or cannulation of the right atrium via the femoral, jugular or subclavian vein.

13. Cardiopulmonary bypass is initiated.

14. When aortic occlusion is required, the CPB blood flow is momentarily reduced to 25% and using the inflation syringe, the balloon is inflated to contact the vessel wall. After initial contact, under careful TEE monitoring (Fluoroscopic visualization of balloon inflation may also be used if desired). An additional fluid should be added slowly until appropriate

occlusion and stability are achieved. Inflation volume of 35cc or balloon pressure of 400mmHg should not be exceeded. Full blood flow rate is then resumed. A volume of 10cc will result in a balloon diameter of 25-26mm.

Inappropriate venous drainage may cause the heart to eject against the balloon during inflation, resulting in balloon movement during inflation.

The right and left radial/brachial pressure waveforms and arterial waveforms are closely monitored and evaluated continuously during the period of balloon inflation, and the position of the balloon observed with TEE. Any change in the right radial/brachial waveform (in comparison to the left) may indicate that the occlusion balloon is obstructing the origin of the innominate artery, requiring deflation and repositioning.

15. Cardioplegic solution is administered through the aortic root line **109** as required to provide arrest. Prior to the delivery of cardioplegia, the aortic vent should be stopped for 1-2 minutes to allow accumulation of blood at the aortic root. The aortic root lumen is then cleared of air by gentle aspiration or gravity blood flow back through the lumen, then the cardioplegia solution can be administered through the lumen. The cardioplegia flow should begin slowly, and gradually be increased to the desired flow and pressure. The position of the occluding balloon should be closely observed for shifts during the delivery of cardioplegia, and verified again after cessation of the cardioplegia delivery.

16. The aortic root lumen may be opened to the CPB vent line when cardioplegia is not being administered. A safety valve should be inserted into the vent line to prevent more than 80mmHg of vacuum. It is recommended that the surgical field be flushed with CO2 to prevent air introduction.

17. When aortic occlusion is no longer required, fluid from the balloon should be gently aspirated until the total volume used for inflation is returned to the syringe. The stopcock to the balloon inflation lumen should be closed to assure the balloon is collapsed against the catheter. The catheter may now be withdrawn at the conclusion of the bypass.

18. To remove the catheter after conclusion of bypass, the catheter is withdrawn to indicator mark indicating distal blood outlet port is two inches from arterial access incision, clamp cannula at indicator mark using tube-occluding forceps. A sterile towel should be wrapped around the catheter covering exposed portion of catheter between indicator mark and distal end of catheter. This will provide controlled blood loss during cannula withdrawal. If obturator reinsertion is desired, obturator may now be inserted back into cathether up to

position of clamp. Clamp should be removed and obturator advanced to incision site. The catheter (with obturator) can now be withdrawn and access incision closed.

Should change out of the catheter be required during cardiopulmonary bypass, the following steps are followed. This is a representative process for using the catheter of this invention given as a stepwise approach.

1. Completely deflate occlusion balloon.

2. Insert 0.035 x 180-cm stiff guide wire through hemostatic valve attached to aortic root lumen, adjust valve to control bleed-back while still allowing free movement of guide wire. Use TEE and/or fluoroscopic imaging to position tip of guide wire in ascending aorta at tip of aortic cannula.

3. Prepare new catheter for introduction as specified in directions for use in step 3, above.

4. Discontinue arterial blood flow from cardiopulmonary bypass machine.

5. Clamp catheter at 3/8 tubing section provided for clamping. Clamp cardiopulmonary bypass machine arterial line just distal of the catheter connection. Separate connection between the catheter and cardiopulmonary bypass machine arterial line.

6. Withdraw catheter over guide wire and remove it from guide wire taking care not to change position of guide wire in aorta. Use of a soft-jaw clamp to control blood loss at femoral artery insertion site is recommended.

7. Advance new catheter over guide wire, balloon first into the femoral artery. The catheter (with obturator) is advanced in a retrograde fashion up the lilac artery, abdominal aorta and thoracic aorta. When the catheter has been advanced past the indicator markers, the obturator can be removed from the catheter, which is de-aired by allowing back bleeding, and then clamped at the 3/8 tubing area provided for clamping. The cardiopulmonary bypass machine arterial line may now be connected to the catheter, taking care not to introduce any air into the line while connecting. Bypass may now be reinitiated.

The catheter of this invention should then be positioned and used as referred to in directions for use for steps number 7 through 18, above.

All references to any patents or articles in this application are to be interpreted to specially incorporate each in this application by reference.

THE SUBJECT MATTER CLAIMED IS:

1. A multichannel catheter useful for delivering extracorporeal blood to a mammal in need thereof by insertion into a blood vessel of the mammal, which catheter has a defined length with distal and proximal ends and comprises

a central, first channel defined by a surrounding wall extending substantially the length of the catheter, which channel is closed at its distal end;

a second channel (i) extending substantially the length of the catheter parallel to the first channel but independent thereof, (ii) being integrated into the wall of the first channel, and (iii) being open at its distal end;

a plurality of openings for the outflow of blood in the wall of the catheter communicating only with said first channel;

an inflatable bladder integrated into the distal end of the catheter between the openings for the outflow of blood and the second channel distal opening;

a third channel (i) extending substantially the length of said catheter integrated into the wall of the first channel; (ii) being parallel to the first and second channels but independent thereof, and (iii) having a distal opening in fluid communication with the interior of the inflatable bladder; and

a solid flexible shaft slidably engageable into the first channel extending substantially the length of the first channel.

2. The catheter of claim 1, wherein the closed distal end of the first channel is located proximal of the inflatable bladder.

3. The catheter of claim 1, wherein the proximal end of the first channel is designed to receive extracorporeal blood from a cardiopulmonary machine.

4. The catheter of claim 3 wherein the plurality of openings communicating with the first channel have an outflow capacity that exceeds the capacity for the blood to flow into the proximal end of the first channel.

5. The catheter of claim 1, wherein the proximal end of the third channel is designed to import or export fluid for inflating or deflating the inflatable bladder, respectively.

6. The catheter of claim 1, wherein the proximal end of the second channel is designed to receive cardioplegia solution, optical fibers, or a guidewire to aid in positioning the distal tip of the catheter in the ascending aorta of the mammal.

7. The catheter of claim 1, wherein the portion of the catheter extending beyond the closed distal end of the first channel is long enough to transcend the aortic arch when the inflatable bladder is positioned to block the ascending aorta.

8. The catheter of claim 7, wherein the portion of the catheter extending beyond the closed distal end of the first channel includes only the second and third channels.

9. The catheter of claim 1, wherein at least one opening in the first channel is elongate with the length of the elongate opening being parallel to the length of the catheter.

10. The catheter of claim 1, wherein the catheter is of a length that is sufficient to allow insertion into a femoral artery and positioning such that the distal end of the catheter is located in the ascending aorta such that the openings communicating with the first channel are positioned along the mid to distal portion of the catheter.

11. The catheter of claim 1, wherein markings are positioned near the proximal end of the catheter to mark the distance from the distal end of the catheter.

12. The catheter of claim 1, wherein the shaft has a handle on its proximal end for positioning the shaft along the length of the first channel.

13. The catheter of claim 1, wherein the second and third channels are positioned about 180° from each other in the wall of the first channel.

14. The catheter of claim 1, wherein the inflatable bladder, when inflated and viewed longitudinally, is of a cylindrical shape.

15. A process for preparing for cardiovascular surgery in a mammal, which process comprises

(A) inserting into a femoral artery of the mammal the distal end of the catheter of claim 1 with the flexible shaft slidingly engaged in the first channel to prevent backflow of blood,

(B) positioning the catheter so that the inflatable bladder is located in the ascending aorta, and

(C) removing the flexible shaft from the first channel to allow the first channel to be connected to a cardiopulmonary machine to pump blood into the first channel at the proximal end of the first channel.

16. The process of claim 15, which further comprises

(D) inserting at least one cannula into a mammal's peripheral veins to position it so the distal open end of the cannula is adjacent the vena cava regions of the mammal's heart and the proximal end of the cannula is attached to a cardiopulmonary machine through a pump wherein the cardiopulmonary machine comprises a blood oxygenation means fluidly connected to the pump,

(E) providing a source of oxygenated blood from the cardiopulmonary machine to the proximal end of the first channel;

(F) providing a source of cardioplegia fluid to the proximal end of the second channel in an amount sufficient to reach the coronary arteries and reduce the heart rate;

(G) providing a source of fluid for inflating the inflatable bladder to the proximal end of said third channel to inflate the inflatable bladder to block the flow of blood to the heart;

(H) pumping oxygen-rich blood through the first channel and out the first channel openings at a rate sufficient to maintain the mammal's metabolism and perfusion; and

(I) removing oxygen-depleted blood from the mammal's vena cavae regions through the femoral vein cannula.

17. The process of claim 16 that further comprises performing cardiovascular surgery as needed and continuing to pump the oxygen-rich blood to the mammal at a rate sufficient to maintain the mammal's metabolism and perfusion.

18. A process for preparing a multichannel catheter, which process comprises:

(A) extrusion molding a catheter having distal and proximal ends wherein the catheter comprises

(1) a central, first channel extending substantially the length of the catheter and being defined by the wall of the catheter;

(2) a second channel extending the entire length of the catheter, being integrated into the wall of the first channel;

(3) a third channel extending substantially the length of the catheter parallel to the first and second channels but independent thereof and being integrated into the wall of the first channel and spaced from the second channel,

(B) integrating an inflatable bladder into the distal end of the catheter so that the distal outlet of the third channel communicates with the interior of the bladder; and

(C) slidingly inserting a flexible, elongated, shaft into the central first channel, a handle for positioning the shaft within the central channel.

19. A multichannel catheter useful for extracorporeal circulation of the blood to a patient undergoing cardiovascular surgery, which catheter comprises

at least three independent channels and an expandable balloon at one end of the catheter;

a first widest channel of a size to permit delivery of an amount of blood to the patient that is sufficient to support the patient metabolism and perfusion throughout the surgery, wherein the first channel has a series of outlet ports along at least a portion of the wall of the channel;

a second channel, narrower than the first channel and integrated into the wall of the first channel, the second channel suitable at least for delivering cardioplegia solution to the heart or for venting the left heart;

a third channel also narrower than the first channel and integrated into the wall of the first channel, said third channel suitable for delivery of fluid to the balloon for expansion when positioned in the ascending aorta to occlude the flow of blood,

and

a flexible shaft slidably inserted into the first channel of the catheter and having a handle located at the proximal end of the shaft for slidably positioning the shaft along the length of the first channel to block at least one outlet port.

20. An obturator useful for slidably inserting into a blood-flow catheter, which oburator comprises a flexible shaft made of medical grade polymeric materials having a length of

about 40 cm to about 120 cm, having a cross-sectional diameter of less than about 28.2 French, having a Durometer rating of about 40A to about 90A, and having a cross-sectional design to snugly and slidingly fit into a blood flow catheter channel to block the flow of blood through the channel.

5

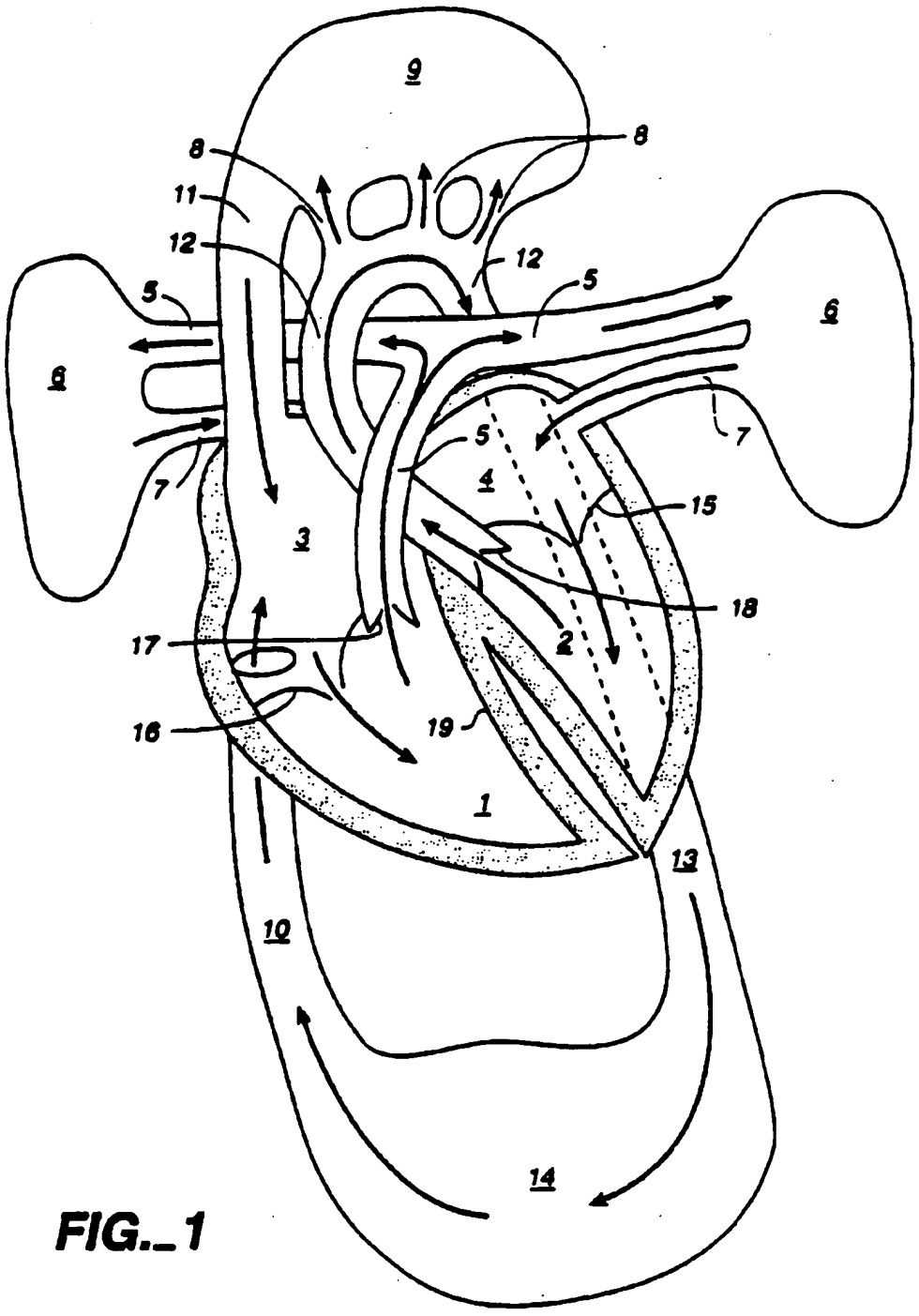


FIG._1

FIG._2

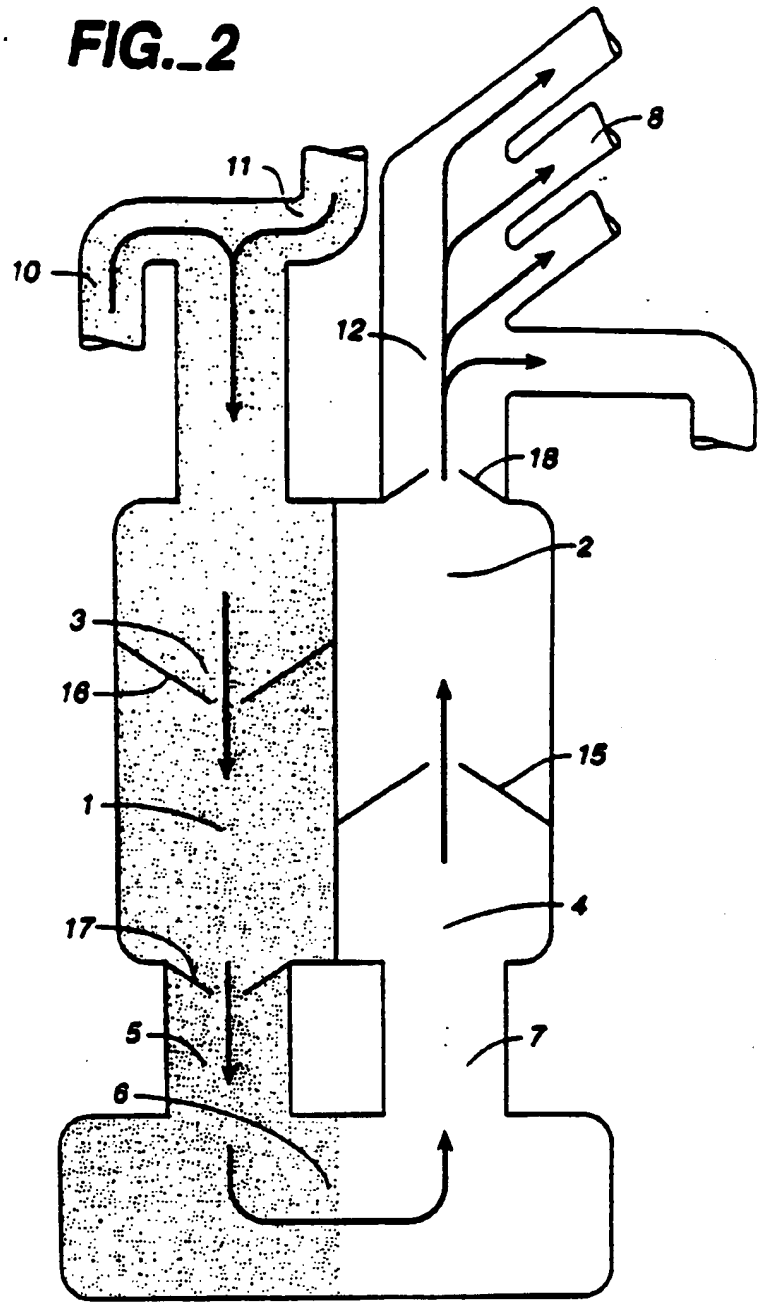
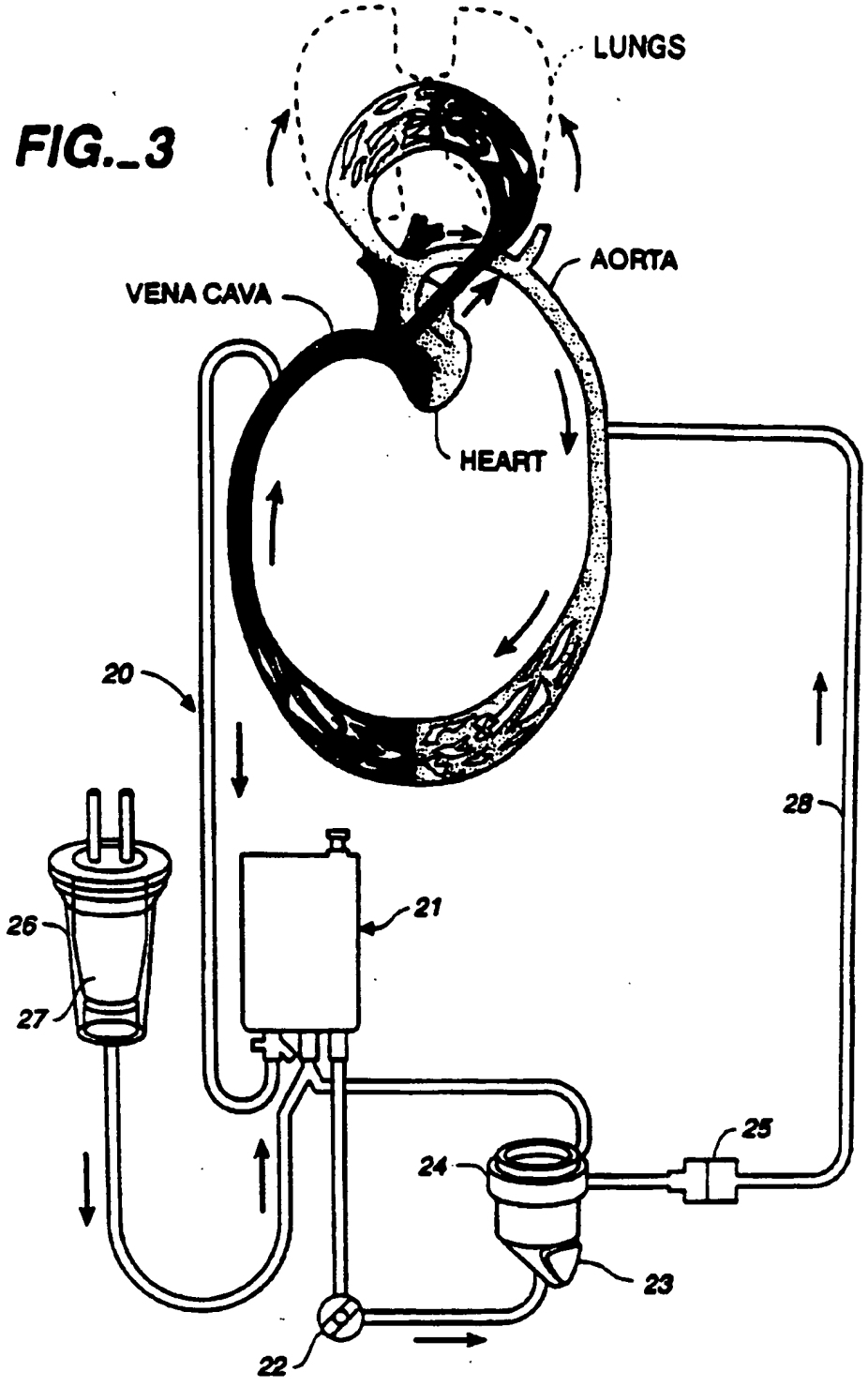


FIG._3



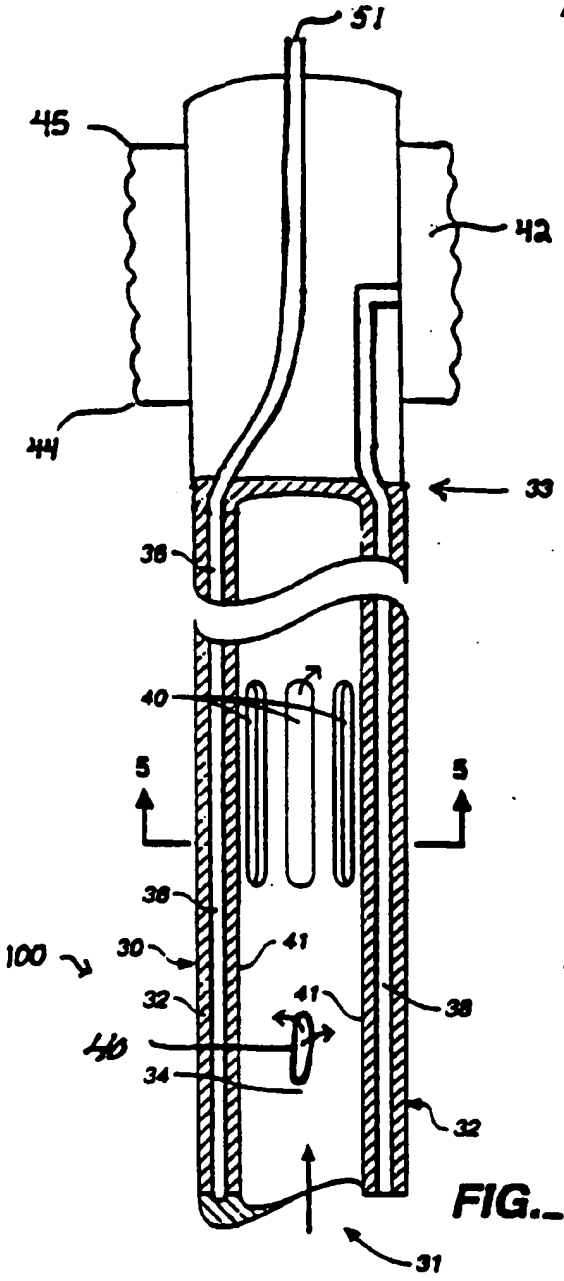


FIG._4

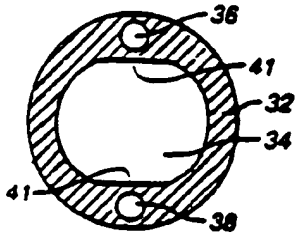


FIG._5A

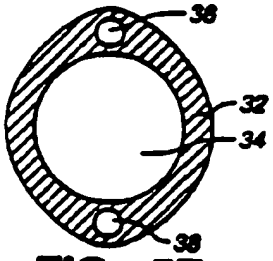


FIG._5B

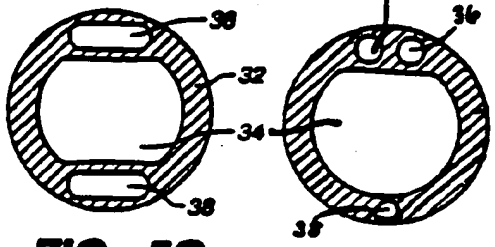


FIG._5C

FIG._5D

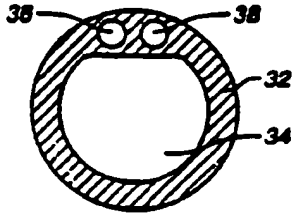


FIG._5E

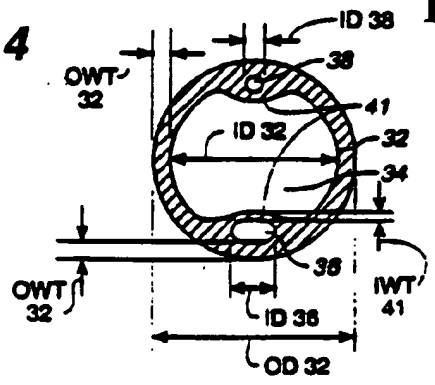


FIG._7

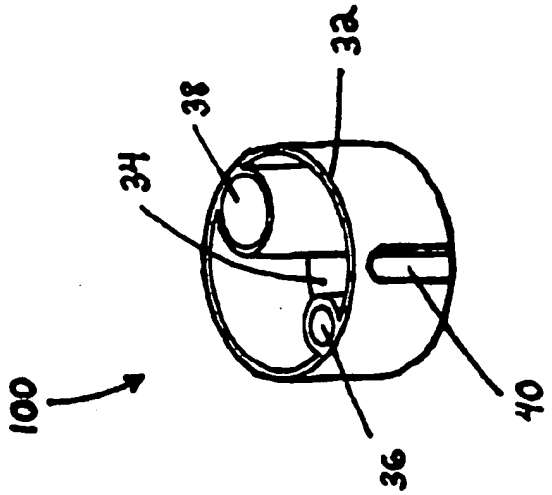


Figure 6B

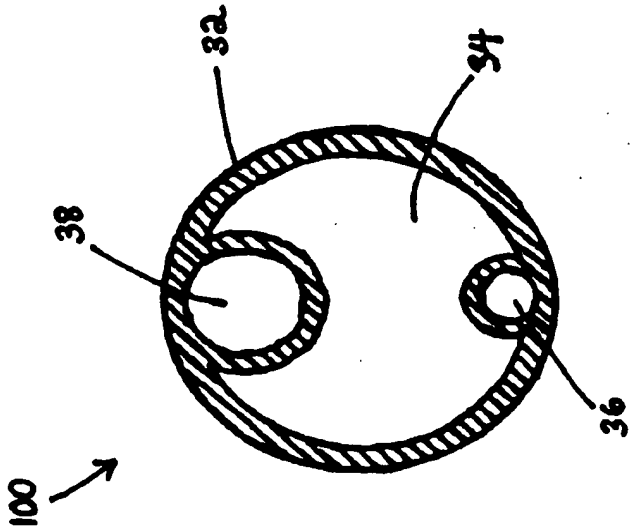


Figure 6A

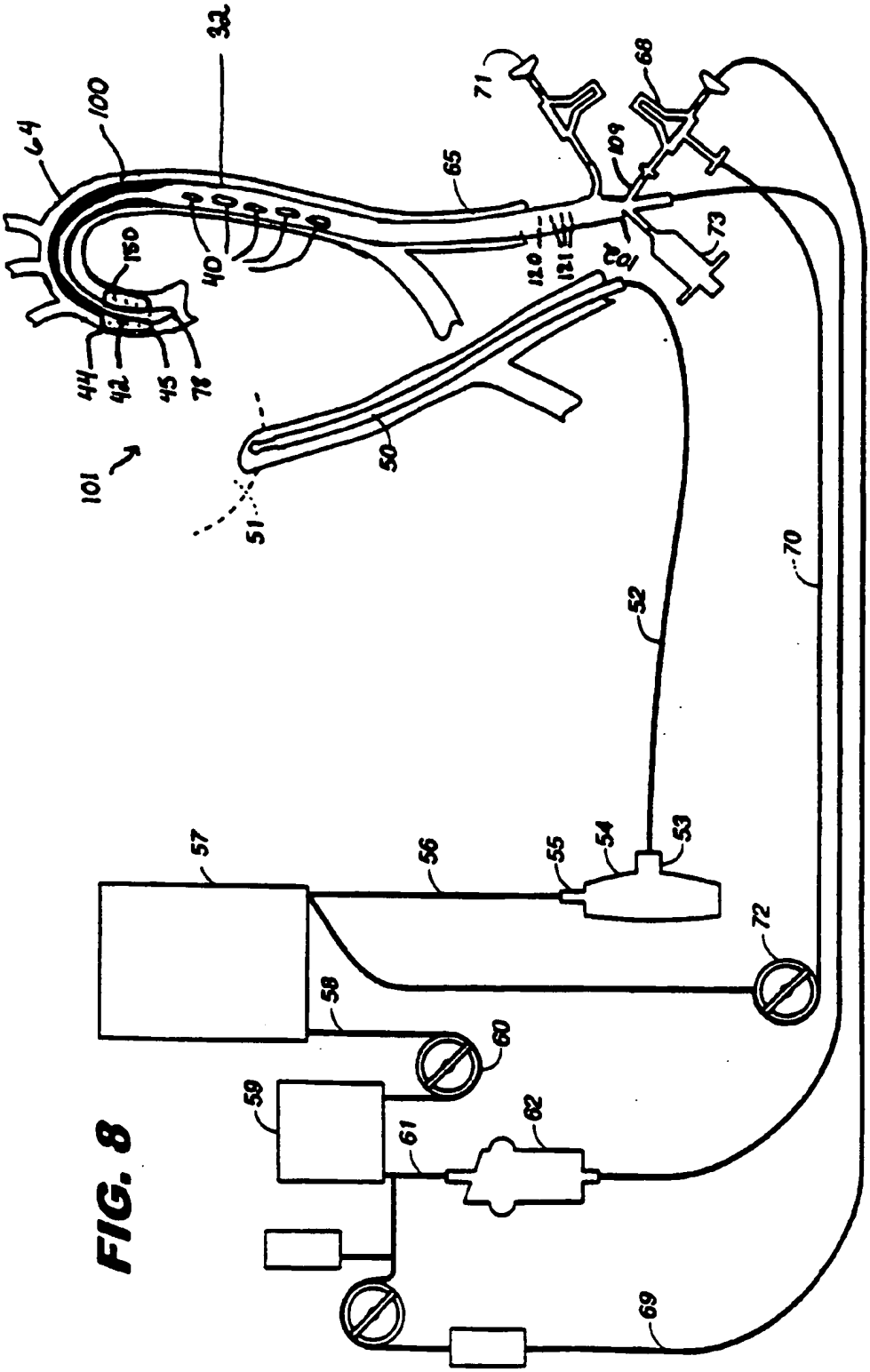

32
100
64
71
68
109
65
73
160
40
110
111
81
44
42
45
78
50
101
51
70
52
57
56
55
54
53
72
58
60
59
62
61
69

FIG. 8

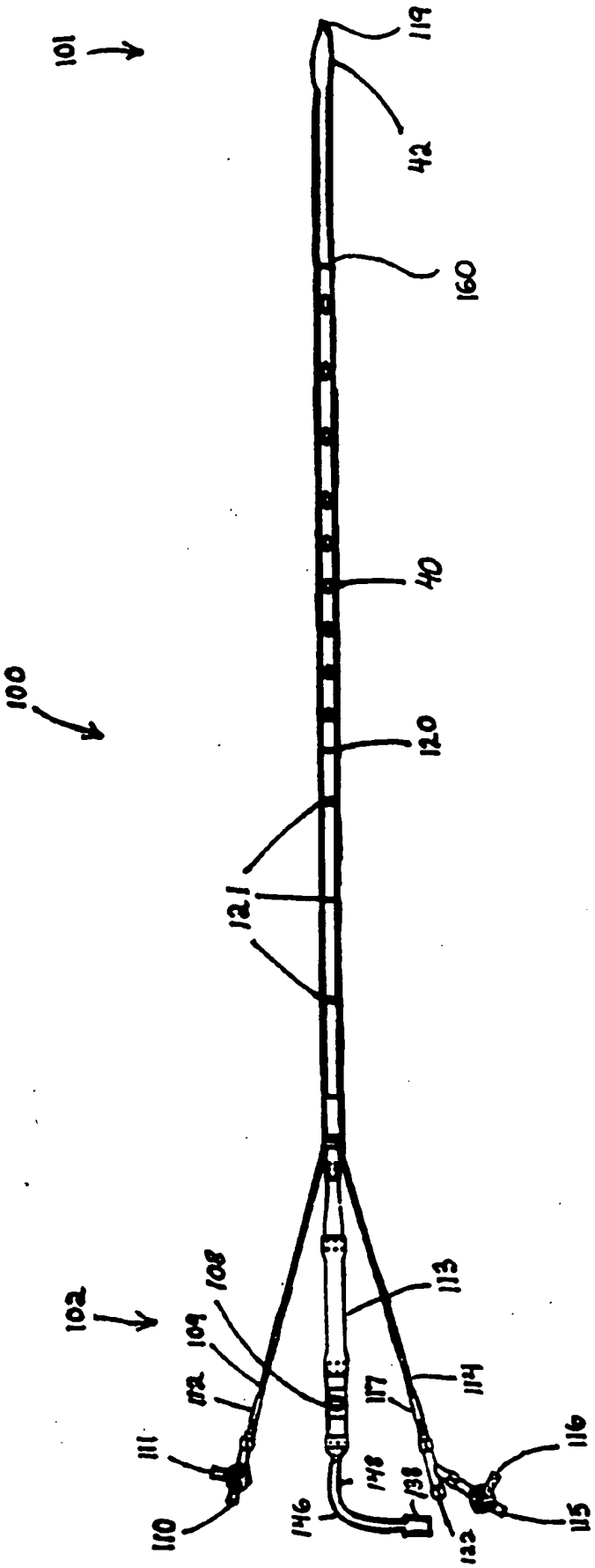
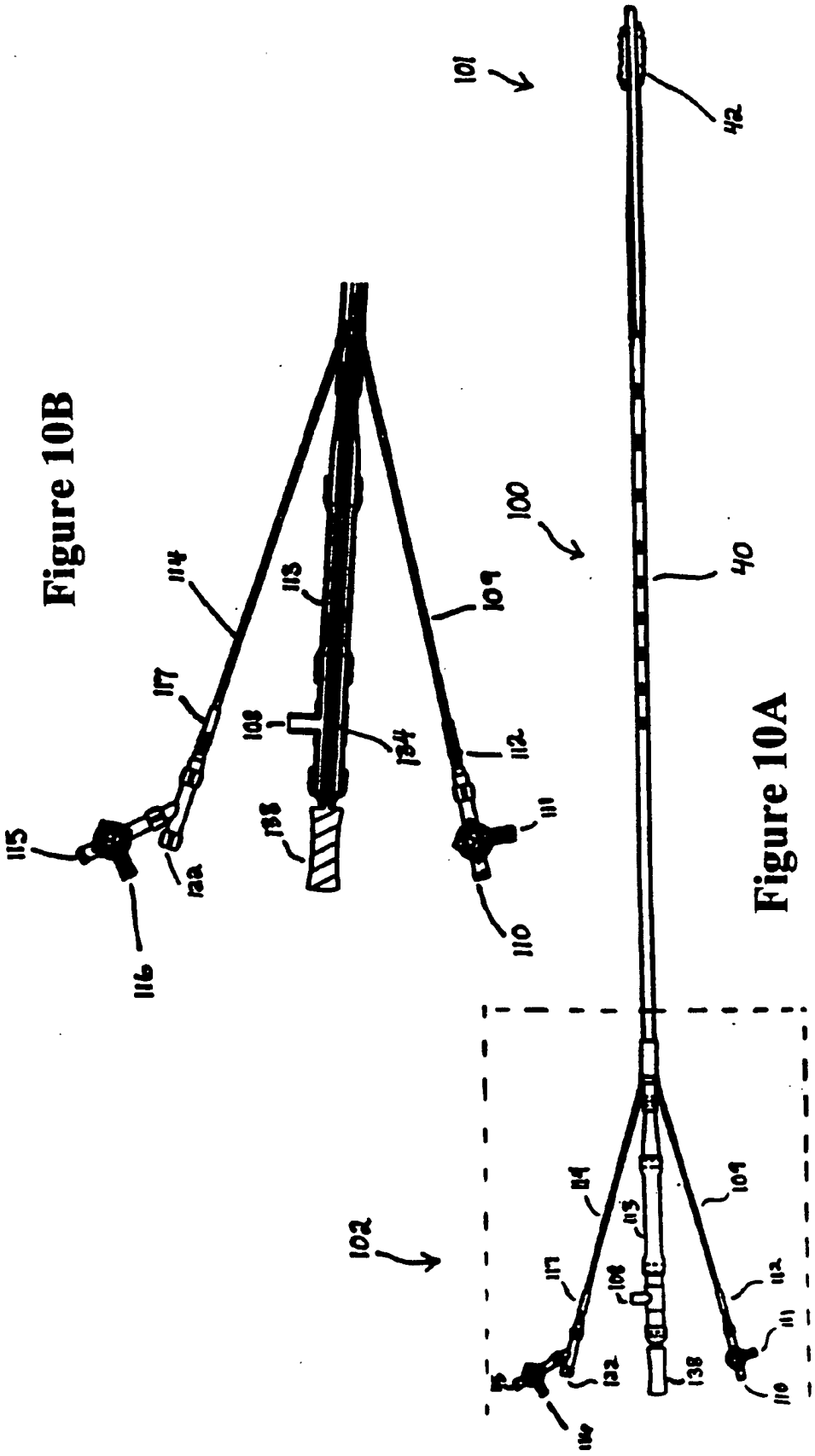

101
119
42
160
40
120
100
121
102
108
109
112
113
114
117
111
116
148
138
146
110
115
122

Figure 9


101
42
100
40
114
113
109
117
108
134
112
115
111
116
110
102
Figure 10B
Figure 10A

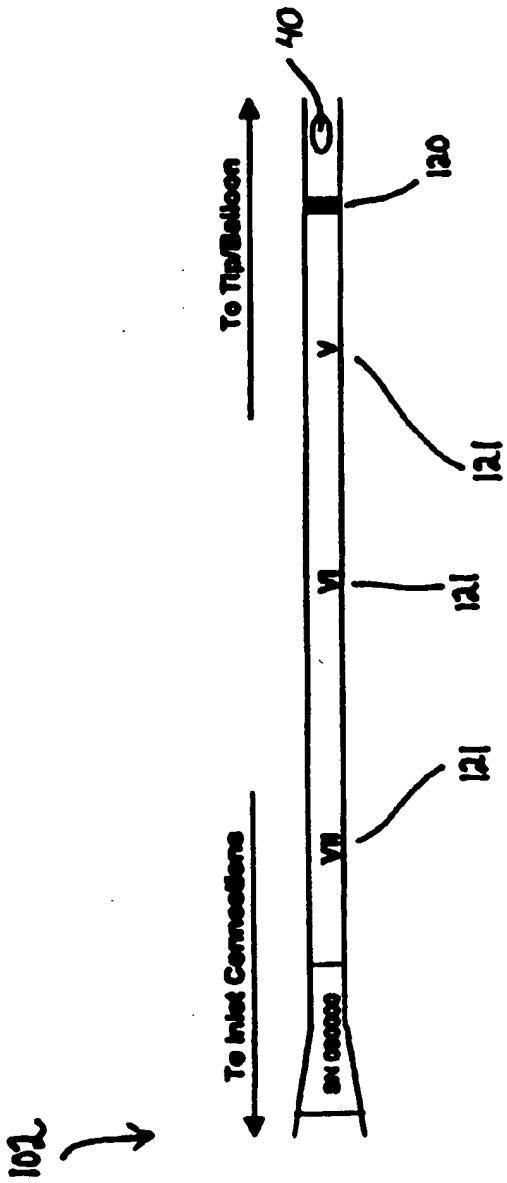

40
120
To Tip/Balloon
V
121
VI
121
121
VII
To Inlet Connectors
102

Figure 11

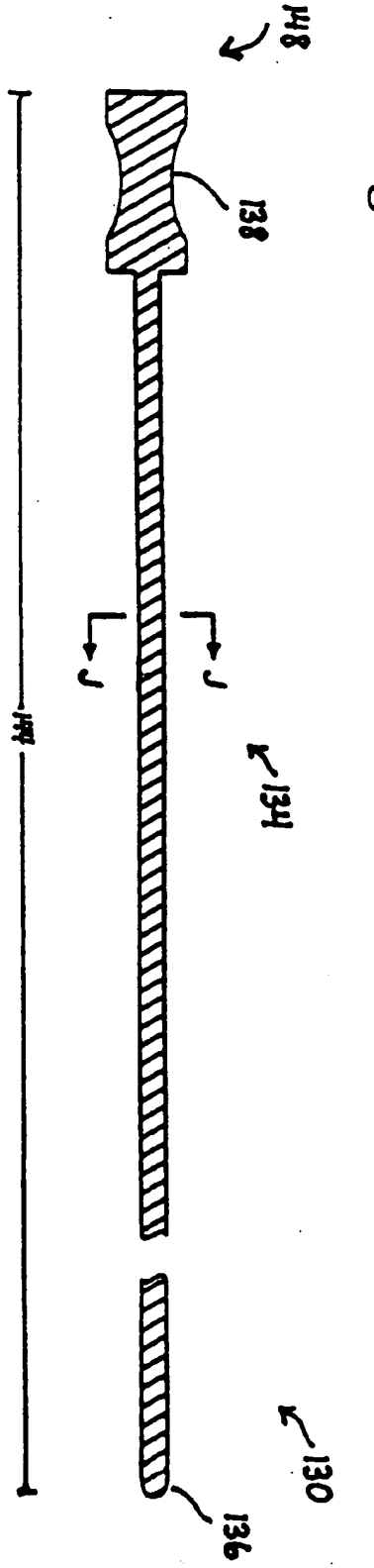


Figure 12A

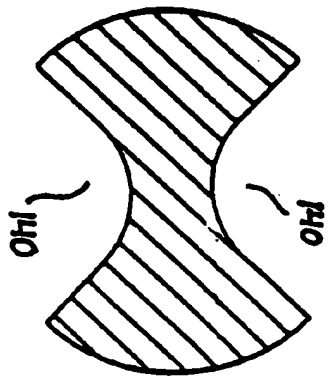


Figure 12B

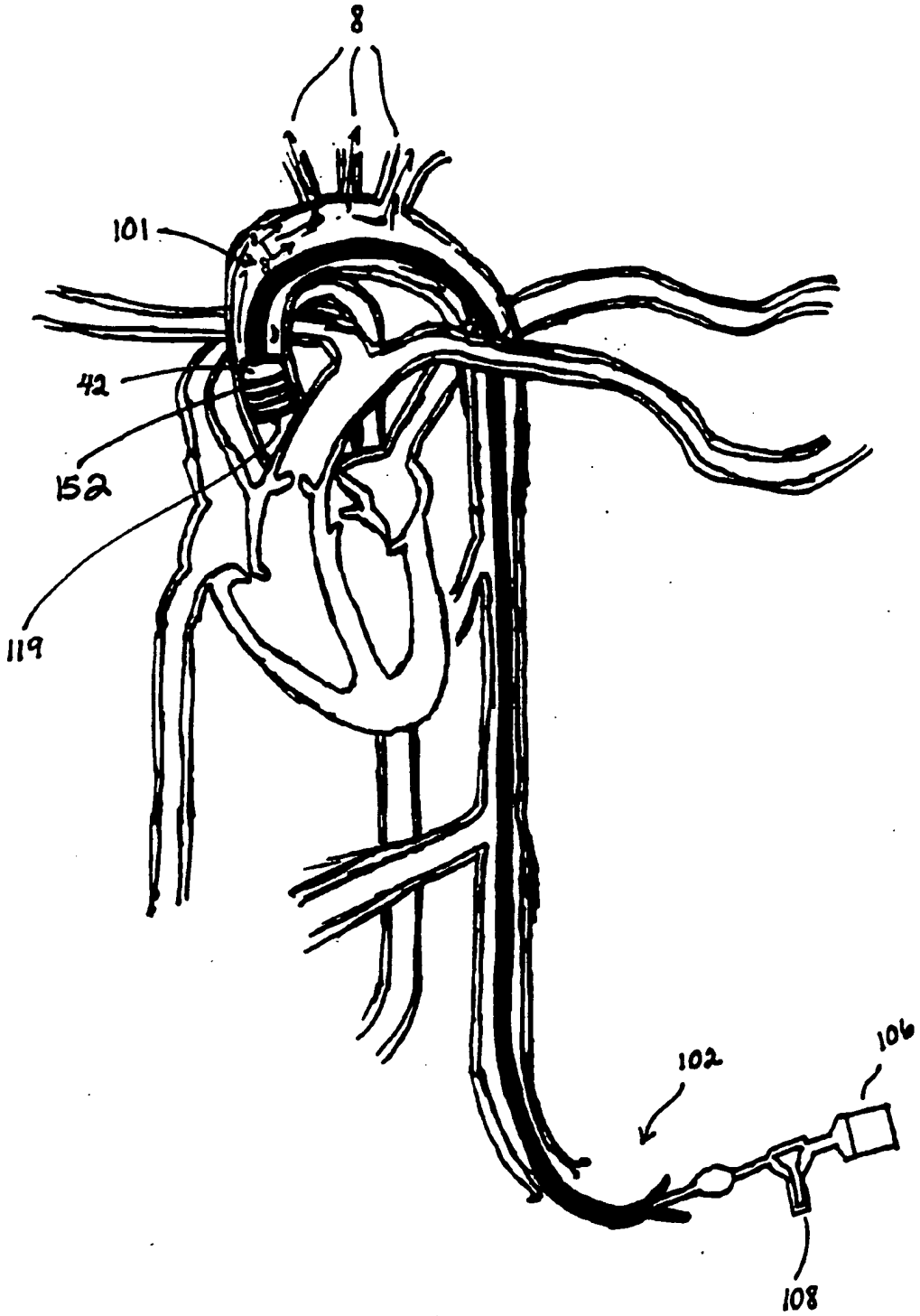


FIG. 13

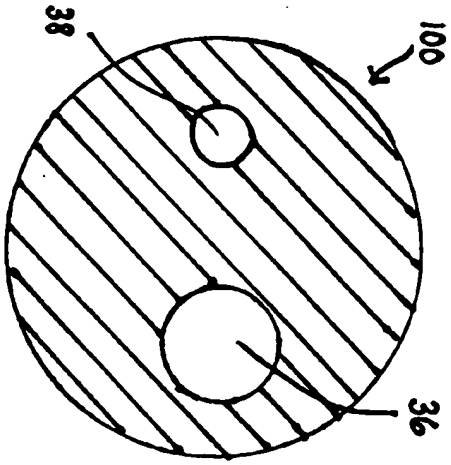


Figure 14A

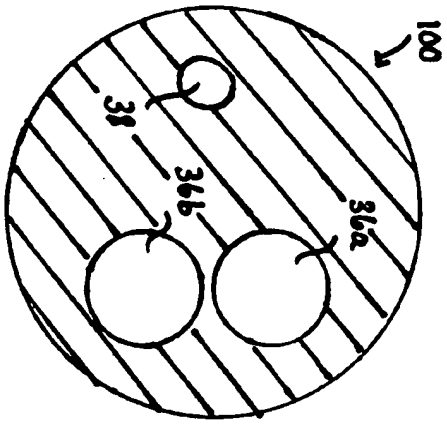


Figure 14B

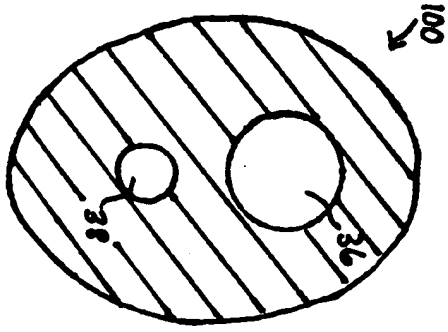


Figure 14C

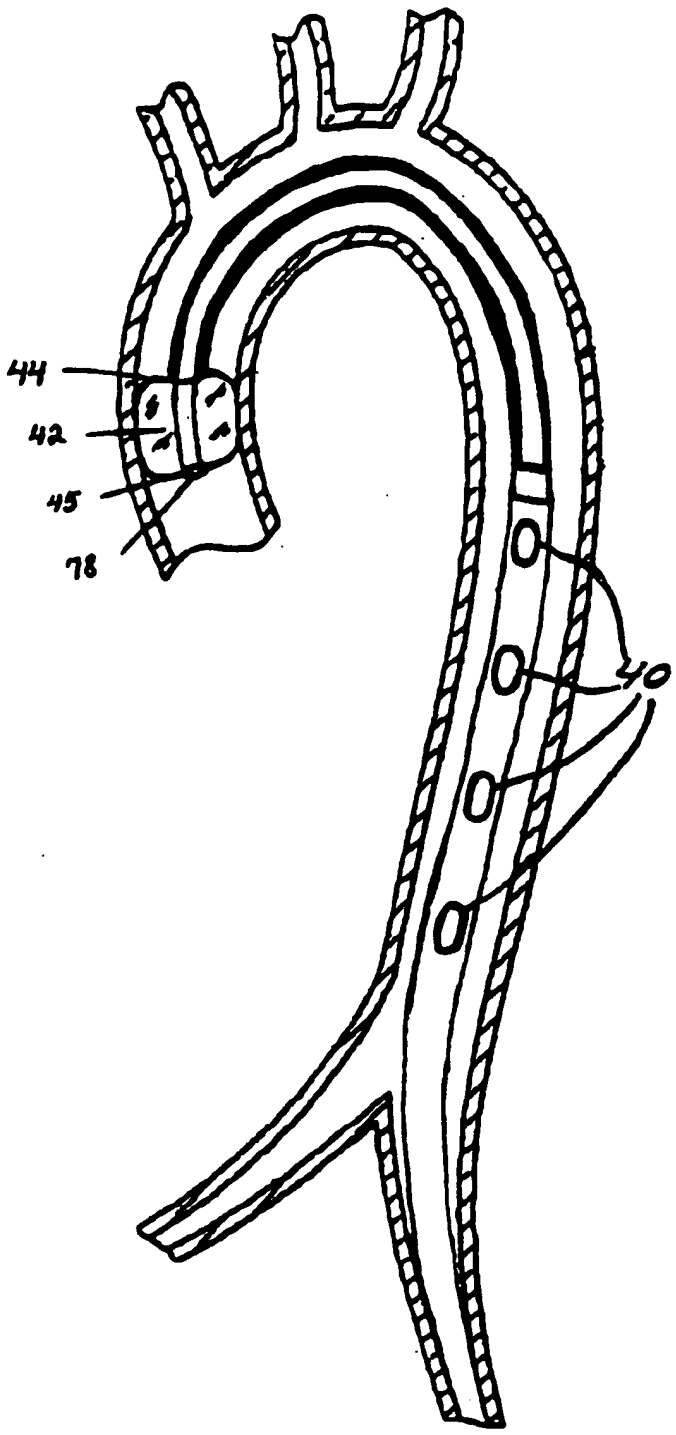


Figure 15

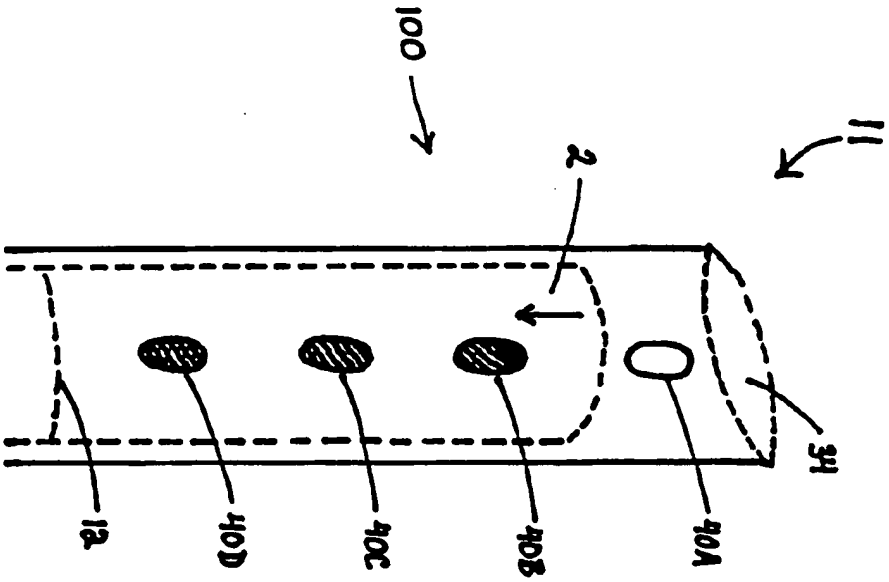


Figure 16

(12) INTERNATIONAL APPLICATION PUBLISHED UNDER THE PATENT COOPERATION TREATY (PCT)

(19) World Intellectual Property Organization
International Bureau

(43) International Publication Date
24 August 2000 (24.08.2000)

PCT

(10) International Publication Number
WO 00/48659 A3

(51) International Patent Classification[7]: A61M 25/10

(21) International Application Number: PCT/US00/04374

(22) International Filing Date: 18 February 2000 (18.02.2000)

(25) Filing Language: English

(26) Publication Language: English

(30) Priority Data:
60/120,038 19 February 1999 (19.02.1999) US

(71) Applicant *(for all designated States except US)*: **ENDOSCOPIC TECHNOLOGIES, INC.** [US/US]; Suite 100, 4115 Blackhawk Plaza Circle, Danville, CA 94506 (US).

(72) Inventors; and

(75) Inventors/Applicants *(for US only)*: **BERTOLERO, Arthur, A.** [US/US]; 155 Sunhaven Road, Danville, CA 94506 (US). **BERTOLERO, Raymond, S.** [US/US]; 130 Windover, Danville, CA 94506 (US). **RIEBMAN, Jerome, B.** [US/US]; 1291 Brookings Lane, Sunnyvale, CA 94087 (US).

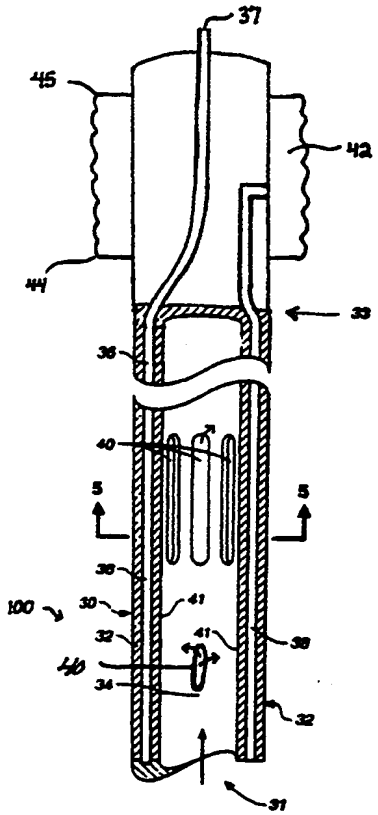
(74) Agents: **MORAN, Tom, M.**; Cooley Godward LLP, Five Palo Alto Square, 3000 El Camino Real, Palo Alto, CA 94306-2155 et al. (US).

(81) Designated States *(national)*: AE, AL, AM, AT, AU, AZ, BA, BB, BG, BR, BY, CA, CH, CN, CR, CU, CZ, DE, DK, DM, EE, ES, FI, GB, GD, GE, GH, GM, HR, HU, ID, IL, IN, IS, JP, KE, KG, KP, KR, KZ, LC, LK, LR, LS, LT, LU, LV, MA, MD, MG, MK, MN, MW, MX, NO, NZ, PL, PT, RO, RU, SD, SE, SG, SI, SK, SL, TJ, TM, TR, TT, TZ, UA, UG, US, UZ, VN, YU, ZA, ZW.

(84) Designated States *(regional)*: ARIPO patent (GH, GM, KE, LS, MW, SD, SL, SZ, TZ, UG, ZW), Eurasian patent

[Continued on next page]

(54) Title: MULTICHANNEL CATHETER WITH OBTURATOR



(57) **Abstract:** This invention is a multichannel catheter for extracorporeal circulation of blood to a patient undergoing cardiovascular treatments or surgery. The catheter has three independent channels, an obturator and an expandable balloon at one end of the catheter. The first channel is the largest and is of a size that allows for delivery of blood through outlet parts in the wall of the first channel to a patient in an amount sufficient to maintain the patient's metabolism and perfusion throughout the treatment or surgery. The obturator is longitudinally insertable into the first channel. A second channel, smaller than the first, is integrated into the wall of the first channel, and is suitable for delivering a biologically active fluid (e.g., for cardioplegia) to the heart and/or venting the left heart. A third channel, also smaller than the first, is integrated into the wall of the first channel, and suitable for delivering a fluid to the balloon for its expansion when positioned in the ascending aorta to occlude the flow of blood to the heart. The catheter provides an improved means of preparing for or performing cardiovascular surgery on a patient using a cardiopulmonary machine for extracorporeal circulation of blood. The catheter is particularly useful for cardiac surgery.

WO 00/48659 A3

(AM, AZ, BY, KG, KZ, MD, RU, TJ, TM), European patent (AT, BE, CH, CY, DE, DK, ES, FI, FR, GB, GR, IE, IT, LU, MC, NL, PT, SE), OAPI patent (BF, BJ, CF, CG, CI, CM, GA, GN, GW, ML, MR, NE, SN, TD, TG).

Published:

— *With international search report.*

(88) Date of publication of the international search report:
25 January 2001

For two-letter codes and other abbreviations, refer to the "Guidance Notes on Codes and Abbreviations" appearing at the beginning of each regular issue of the PCT Gazette.

PCT WORLD INTELLECTUAL PROPERTY ORGANIZATION
International Bureau

INTERNATIONAL APPLICATION PUBLISHED UNDER THE PATENT COOPERATION TREATY (PCT)

(51) International Patent Classification 6 : A61N 5/10, A61M 25/10 — A1

(11) International Publication Number: **WO 98/01185**

(43) International Publication Date: 15 January 1998 (15.01.98)

(21) International Application Number: PCT/NL97/00386

(22) International Filing Date: 4 July 1997 (04.07.97)

(30) Priority Data:
1003529 5 July 1996 (05.07.96) NL

(71) Applicant *(for all designated States except US)*: B.V. OPTISCHE INDUSTRIE "DE OUDE DELFT" [NL/NL]; Postbus 72, NL-2600 MD Delft (NL).

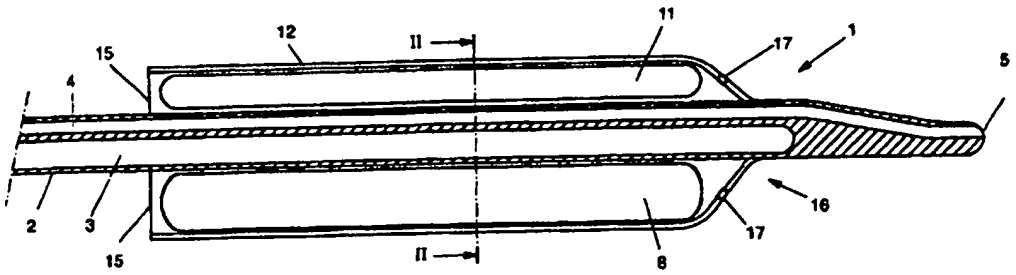
(72) Inventors; and
(75) Inventors/Applicants *(for US only)*: LÖFFLER, Edgar, German [DE/DE]; Bresserbergstrasse 72, D-47533 Kleve (DE). VISSCHER, Arie, Luite [NL/NL]; W. Banninglaan 33, NL-3972 SJ Driebergen (NL).

(74) Agent: VAN DER BURG, Louis; B.V. Optische Industrie "De Oude Delft", Postbus 72, NL-2600 MD Delft (NL).

(81) Designated States: JP, US, European patent (AT, BE, CH, DE, DK, ES, FI, FR, GB, GR, IE, IT, LU, MC, NL, PT, SE).

Published
With international search report.
Before the expiration of the time limit for amending the claims and to be republished in the event of the receipt of amendments.
In English translation (filed in Dutch).

(54) Title: CATHETER HAVING CENTERING MEANS



(57) Abstract

A catheter comprising an elongated tube having a first channel for the guiding of a radioactive element and a second channel for the passage of a guide wire for the catheter, in which the elongated tube is provided on its outer circumference near its distal end with temporarily activatable centering means, the centering means being surrounded by recanalization means, and the centering means comprising a plurality of elongated balloons which are inflatable by fluid fed through at least one third channel and, in operation, allow the recanalization means to expand to form an elongated body, with respect to which the first channel is centered.

FOR THE PURPOSES OF INFORMATION ONLY

Codes used to identify States party to the PCT on the front pages of pamphlets publishing international applications under the PCT.

AL	Albania	ES	Spain	LS	Lesotho	SI	Slovenia
AM	Armenia	FI	Finland	LT	Lithuania	SK	Slovakia
AT	Austria	FR	France	LU	Luxembourg	SN	Senegal
AU	Australia	GA	Gabon	LV	Latvia	SZ	Swaziland
AZ	Azerbaijan	GB	United Kingdom	MC	Monaco	TD	Chad
BA	Bosnia and Herzegovina	GE	Georgia	MD	Republic of Moldova	TG	Togo
BB	Barbados	GH	Ghana	MG	Madagascar	TJ	Tajikistan
BE	Belgium	GN	Guinea	MK	The former Yugoslav Republic of Macedonia	TM	Turkmenistan
BF	Burkina Faso	GR	Greece			TR	Turkey
BG	Bulgaria	HU	Hungary	ML	Mali	TT	Trinidad and Tobago
BJ	Benin	IE	Ireland	MN	Mongolia	UA	Ukraine
BR	Brazil	IL	Israel	MR	Mauritania	UG	Uganda
BY	Belarus	IS	Iceland	MW	Malawi	US	United States of America
CA	Canada	IT	Italy	MX	Mexico	UZ	Uzbekistan
CF	Central African Republic	JP	Japan	NE	Niger	VN	Viet Nam
CG	Congo	KE	Kenya	NL	Netherlands	YU	Yugoslavia
CH	Switzerland	KG	Kyrgyzstan	NO	Norway	ZW	Zimbabwe
CI	Côte d'Ivoire	KP	Democratic People's Republic of Korea	NZ	New Zealand		
CM	Cameroon			PL	Poland		
CN	China	KR	Republic of Korea	PT	Portugal		
CU	Cuba	KZ	Kazakstan	RO	Romania		
CZ	Czech Republic	LC	Saint Lucia	RU	Russian Federation		
DE	Germany	LI	Liechtenstein	SD	Sudan		
DK	Denmark	LK	Sri Lanka	SE	Sweden		
EE	Estonia	LR	Liberia	SG	Singapore		

CATHETER HAVING CENTERING MEANS

The present invention relates to a catheter comprising an elongated tube having a first channel for the guiding of a radioactive element and a second channel for the passage of a guide wire for the catheter, the elongated tube being provided with temporarily activatable centering means on its outer circumference near its distal end.

Such a catheter, known from EP-A-0 688 580, is intended for use after a recanalization treatment in which a substantially occluded blood vessel (for example as a result of the depositing of so-called plaque within the lumen of the blood vessel) is stretched by means of an expandable element, such as a fluid-inflatable recanalization balloon, fastened to the distal end of an elongated catheter tube, in order to permit the blood to flow unimpeded again through the stretched blood vessel.

It is frequently found after a relatively short period of time that a new recanalization treatment is necessary because a constriction is again forming in the blood vessel or has already formed. That constriction may be a consequence of tissue developing at the stretched place (known as neointima proliferation), probably due to the fact that the wall of the blood vessel is damaged by the stretching. This formation of tissue can be prevented to a large extent or at least reduced if, during or shortly after the recanalization treatment, the blood-vessel tissue in question is irradiated with ionizing radiation, in particular ß and/or γ radiation.

For such a treatment, the catheter known from EP-A-0 668 580 can be used. The intensity of radiation of the radioactive element introduced decreases greatly the distance. In order not to permit the radiation dose to be too great (damaging of vessel wall) or too low (not the intended reduction of tissue developing at the stretched place), it is important to center the radioactive element accurately in the blood vessel. This is done in the known catheter by centering means in the form of an inflatable balloon which is subdivided by constriction means into a plurality of balloon parts. The constriction means are so dimensioned that the different balloon parts communicate with each other.

Upon such a treatment, therefore, the

recanalization catheter must first of all be brought to the desired place and, after the carrying out of the recanalization treatment, be removed and replaced by the catheter for the guiding of the radioactive element, in which connection, of course, great care must be paid to the fact that the radioactive element can be placed precisely at the place of the earlier recanalization treatment. All in all, a cumbersome and timeconsuming method which must be carried out extremely cautiously, while, also from the standpoint of the patient who must undergo the treatment, it is preferable for it to be carried out as rapidly and efficiently as possible.

The object of the invention then is the provision of such an instrument that the treatment can be carried out in a short time effectively and reliably with as few manipulations as possible.

This is achieved, in accordance with the invention, by a catheter of the type described above in that the centering means are surrounded by recanalization means, the centering means comprising a plurality of elongated balloons which are inflatable by a fluid introduced via a third channel and with respect to which the first channel is centered. By these measures, the recanalization treatment and the radiation treatment of the stretched region of the blood vessel can be carried out with one and the same catheter, in other words rapidly and without loss or time, since a catheter removal action and introduction action are avoided, which also is particularly valued by the patient. Furthermore, the fact that it is not necessary to change the catheter has the particular extra advantage that the centering means are automatically located at precisely the correct, desired place so that, in addition, there is also obtained a guarantee that the radiation will always be carried out at the correct place as well as in the correct manner.

The use of such a catheter for both the recanalization treatment and the radiation treatment results in a longer continuous dwell time of the catheter at the place of treatment than is the case upon use of two catheters introduced one after the other. In this connection, in accordance with a preferred embodiment of the invention, at least one perfusion channel is present which extends within the recanalization means and along the

centering means from the proximal end of the recanalization means and the centering means to the distal end of the recanalization means and the centering means. By these measures the flow of the blood through the treated blood vessel can remain undisturbed to a far-reaching extent, which makes special measures with respect to this generally unnecessary.

The invention will be described in further detail below with reference to the accompanying drawing.

Fig. 1 shows diagrammatically an example of a catheter in accordance with the invention on an enlarged scale, seen in longitudinal section along the line I-I of Fig. 2;

Fig. 2 shows diagrammatically a cross section through a catheter in accordance with the invention in the portion
provided with centering means.

Figs. 1 and 2 diagrammatically show, in longitudinal section and cross section respectively, an example of a distal end of a catheter 1 according to the invention, provided with centering means. The catheter shown comprises a tube 2 having a central channel 3 which in this example is closed at the distal end, and which serves to guide a radioactive radiation source to a predetermined place in a blood vessel in order to irradiate the wall of the blood vessel. The wall of the blood vessel has been or is stretched by recanalization means either previous to or concurrently with the irradiation. The catheter comprises a second lengthwise channel 4 for the passage of a guide wire for the catheter. The second lengthwise channel 4 is open at or near the distal end, as indicated at 5.

In this connection, it is pointed out that different techniques are known for the introduction of a balloon catheter into a blood vessel. As first technique, mention may be made of the so-called fixed-wire system, also known as the "on-the-wire system". A second technique is the socalled "over-the-wire" technique, in which the balloon catheter can be shoved over the guide wire and displaced. In accordance with a third technique, use is made of a balloon catheter, a relatively short segment of

which is provided with a channel having an inlet and an outlet, the guide wire extending through this channel so that the catheter can be pushed along the guide wire. This last technique is generally referred to as the monorail system. This monorail system is also preferably, but not necessarily, used in catheters in accordance with the present invention. In the embodiment shown in Fig. 1, the channel 4 makes the catheter suitable for use of the monorail technique.

The catheter furthermore is provided with centering means and with recanalization means. The centering means comprise a plurality of elongated balloons 6, 7, 8, 9, 10, 11, arranged radially alongside each other around the tube 2, as can best be noted from Fig. 2. The balloons are fastened to the tube and can be inflated by one or more channels arranged in the tube. For this purpose a suitable fluid, which may be either a liquid or a gas or even a combination thereof, can be fed and later removed again via the channels.

For the feeding and removal of fluid to the balloons two channels 13, 14 are formed in the tube in the embodiment shown, which channels are in communication with the inside of the balloons through transverse channels 13a, 13b, 13c and 14a, 14b, 14c respectively.

The elongated balloons are located within recanalization means in a manner similar to that described in the related Dutch patent application NL 1003527 which recanalization means, however, in accordance with the present invention, do not consist of a closed balloon but of a sleeve 12 of supple material. The sleeve 12 can be connected with the outer surface of one or more or even all the balloons, but it can also be connected to the tube 2 by means of suitable connecting means 15, such as, for instance, strips or threads of a suitable material. The connecting means 15 can, for instance, be formed by, starting from an elongated balloon, removing parts of the balloon material at the ends. At the distal end, the connecting means, as shown in 16, can have a streamlined shape in order to avoid pushing up, and are provided with openings 17. The sleeve 12 can be viewed as an elongated balloon open at the front and rear.

The manner of operation of the catheter shown is as follows. First of all, the catheter is brought into a

blood vessel by means of a guide wire in one of the manners known for this, until the part provided with the recanalization means is located at the place of a constriction which is to be treated. The elongated balloons 6 to and including 11 are then inflated via the channels 13 and 14. The balloons, via the sleeve 12, exert an outwardly directed force on the surrounding wall of the blood vessel, which is thereby somewhat stretched, due to which the constriction disappears. The sleeve limits the expansion of the balloons and furthermore has the result that the balloons center the channel 3 with respect to the sleeve, and therefore with respect to the wall of the blood vessel. Therefore, without further centering manipulations, a radioactive element can be pushed in the channel 3 in order to irradiate the wall of the blood vessel at the place of the constriction which was removed. Because the sleeve is open at its ends, and free spaces such as indicated at 18 are present between the balloons, the flow of blood through the blood vessel in question is not interrupted during the treatment.

It is pointed out that the centering manipulation should take place with respect to the channel 3 in which the radioactive element is present in operation. The channel 3 can, to be sure, be located in the center of the tube 2, but frequently this is not the case since the tube 2 also comprises still other channels. In the example shown, the channel 3 lies eccentrically in the tube. In order nevertheless to achieve a good centering, the balloons and/or the connecting means 15 should have a diameter or length respectively adapted to the radial position with respect to the tube. The diameter or length is greater as the balloons or connecting means are closer to the central channel 3. In Fig. 2 it can be seen that the balloons 7 and 8 have the largest diameter and the balloons 10 and 11 the smallest diameter.

It is furthermore pointed out that, on the basis of the foregoing, various modifications will be obvious to the person skilled in the art. One or more elongated balloons can, for instance, consist, as alternative, of a plurality of balloons arranged one behind the other. Furthermore, the sleeve can be constructed of a plurality of annular strips spaced apart from each other, which may or may not be

connected to lengthwise strips.

Furthermore, the channel for the guide wire can be limited to the distal end of the catheter located past the centering means. The channel 4 then extends from the mouth 5 backwards to in front of the distal end of the centering means and there has an opening in the wall for the passage of the guide wire. The rest of the channel 4, which in Fig. 1 extends further in the direction of the proximal end, can then either be absent or be used in order to assume the function of one or both channels 13, 14. The connecting channels 13a, 13b, 13c and/or 14a, 14b, 14c are then of course connected to channel 4, and channels 13 and/or 14 are then superfluous.

CLAIMS

1. A catheter comprising an elongated tube having a first channel for the guiding of a radioactive element, and a second channel for the passage of a guide wire for the catheter, the elongated tube being provided with temporarily activatable centering means on its outer periphery near the distal end, characterized in that the centering means are surrounded by recanalization means, the centering means comprising a number of elongated balloons which are inflatable by a fluid fed through at least one third channel and, in operation, permitting the recanalization means to expand to form an elongated body with respect to which the first channel is centered.

2. A catheter according to Claim 1, characterized by at least one perfusion channel which extends within the recanalization means and along the centering means from the proximal end of the recanalization means and the centering means to the distal end of the recanalization means and the centering means.

3. A catheter according to Claim 1 or 2, characterized in that the recanalization means comprise a sleeve of supple material which lies around the elongated balloons and which is at least partly open at both ends.

4. A catheter according to Claim 3, characterized in that the sleeve is fastened to the outer wall of one or more balloons.

5. A catheter according to Claim 3 or 4, characterized in that the sleeve is connected to the tube by connecting means at least at its ends.

6. A catheter according to Claim 5, characterized in that the sleeve and the connecting means have a smooth streamlined shape at the distal end.

7. A catheter according to anyone of the preceding claims, characterized in that the elongated balloons are distributed radially around the tube and that the free

spaces present between the balloons form perfusion channels.

8. A catheter according to Claim 5, 6, or 7, characterized in that the first channel is arranged eccentrically in the tube and that the length of the connecting means and/or the diameter of the balloons are greater the closer the connecting means and the balloons respectively are to the first channel.

9. A catheter according to anyone of the preceding claims, characterized in that one or more of the elongated balloons are formed by a plurality of balloons placed one behind the other.

10. A catheter according to anyone of the preceding claims, characterized in that the second channel extends exclusively in the distal end of the tube extending in front of the recanalization and centering means.

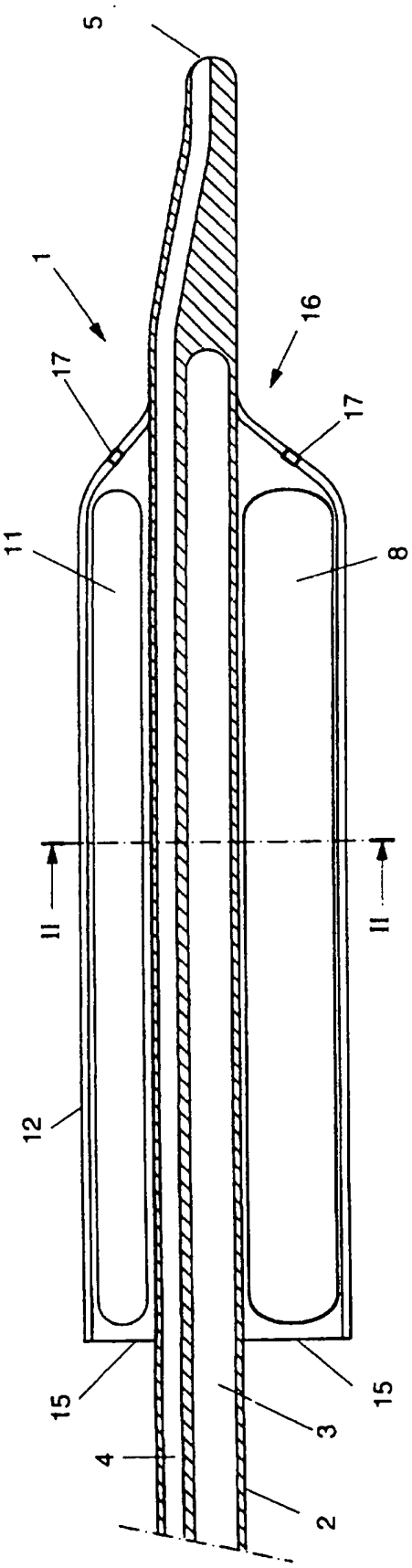

5
1
16
17
17
11
8
II
II
12
15
15
3
4
2

FIG. 1

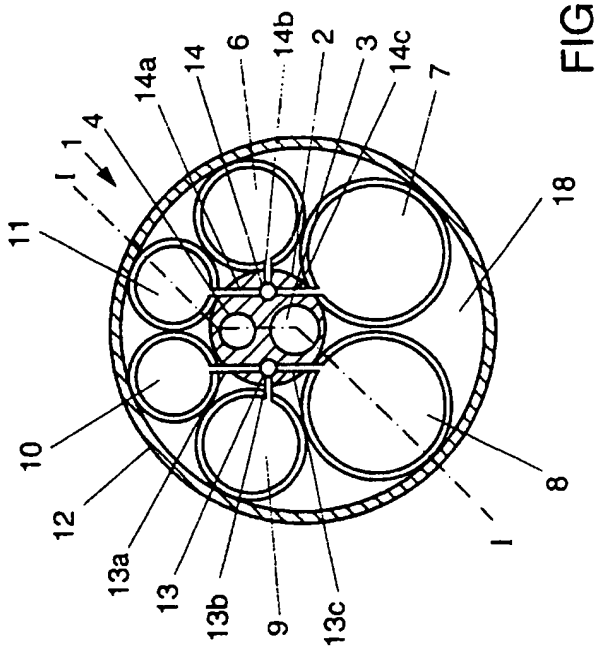

14b
2
3
14c
7
14a
14
6
4
1
I
11
18
10
8
12
I
13a
13
13b
9
13c

FIG. 2

INTERNATIONAL SEARCH REPORT

Internation pplication No
PCT/NL 97/00386

A. CLASSIFICATION OF SUBJECT MATTER
IPC 6 A61N5/10 A61M25/10

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)
IPC 6 A61N A61M

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practical, search terms used)

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category *	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
Y	WO 96 06654 A (TEIRSTEIN) 7 March 1996 see abstract; figures	1-4,7
Y	US 5 501 667 A (VERDUIN) 26 March 1996 see column 3, line 3 - column 4, line 35; figures	1-4,7
A	WO 96 14898 A (OMNITRON INTERNATIONAL) 23 May 1996 see page 11, line 21 - line 31; figures	1,7,8
A	WO 95 26681 A (LIPRIE) 12 October 1995 see abstract; figures 1-5	1
A	US 4 781 681 A (SHARROW) 1 November 1988 see abstract; figures 2,6	1
	-/--	

[X] Further documents are listed in the continuation of box C.

[X] Patent family members are listed in annex.

* Special categories of cited documents :

"A" document defining the general state of the art which is not considered to be of particular relevance

"E" earlier document but published on or after the international filing date

"L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)

"O" document referring to an oral disclosure, use, exhibition or other means

"P" document published prior to the international filing date but later than the priority date claimed

"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention

"X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone

"Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art.

"&" document member of the same patent family

Date of the actual completion of the international search	Date of mailing of the international search report
25 August 1997	03.11.97

Name and mailing address of the ISA	Authorized officer
European Patent Office, P.B. 5818 Patentlaan 2 NL - 2280 HV Rijswijk Tel. (+ 31-70) 340-2040, Tx. 31 651 epo nl. Fax: (+ 31-70) 340-3016	Kousouretas, I

Form PCT/ISA/210 (second sheet) (July 1992)

INTERNATIONAL SEARCH REPORT

Internatior. pplication No
PCT/NL 97/00386

C.(Continuation) DOCUMENTS CONSIDERED TO BE RELEVANT

Category *	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
A	EP 0 567 788 A (INDIANA UNIVERSITY) 3 November 1993 see column 8, line 33 - line 47; figures ---	1
A	DE 91 02 312 U (WEIKL) 25 June 1992 see claim 1; figures -----	1

1

INTERNATIONAL SEARCH REPORT

Information on patent family members

Internation pplication No
PCT/NL 97/00386

Patent document cited in search report	Publication date	Patent family member(s)	Publication date
WO 9606654 A	07-03-96	US 5540659 A	30-07-96
		AU 3497395 A	22-03-96
		CA 2198020 A	07-03-96
		EP 0778788 A	18-06-97
US 5501667 A	26-03-96	NONE	
WO 9614898 A	23-05-96	US 5643171 A	01-07-97
		EP 0740566 A	06-11-96
WO 9526681 A	12-10-95	US 5556389 A	17-09-96
		AU 2192595 A	23-10-95
		CA 2186889 A	12-10-95
		EP 0754010 A	22-01-97
		US 5618266 A	08-04-97
US 4781681 A	01-11-88	AU 2201588 A	16-03-89
		CA 1288654 A	10-09-91
		DE 3880408 A	27-05-93
		EP 0308023 A	22-03-89
		JP 1153149 A	15-06-89
EP 567788 A	03-11-93	US 5306250 A	26-04-94
		CA 2093235 A	03-10-93
		JP 6098938 A	12-04-94
DE 9102312 U	25-06-92	NONE	